

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 51 (90/003,297)
Paper No. 49 (90/003,453)

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MONSANTO COMPANY

Appeal No. 1997-1546
Reexamination Nos. 90/003,297 and 90/003,453¹

HEARD: July 14, 1997

Before WINTERS, WILLIAM F. SMITH, and GRON, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

¹ Merged Reexamination Proceeding for U.S. Patent No. 5,159,135, issued October 27, 1992, based on Application Serial No. 07/575,035, filed August 30, 1990; which is a continuation of Application Serial No. 06/937,384, filed December 3, 1983, now U.S. Patent No. 5,004,863, issued April 2, 1991.

DECISION ON APPEAL²

This is an appeal under 35 U.S.C. § 306 from the decision of the patent examiner that claims 1 through 7 of U.S. Patent No. 5,159,135 are not patentable.

The patented claims read as follows:

1. Cotton seed capable of germination into a cotton plant comprising in its genome a chimeric recombinant gene construction including a foreign gene and promoter and control sequences operable in cotton cells, the chimeric gene construction being effective in the cells of the cotton plant to express a cellular product coded by the foreign gene, the cellular product imbuing the plant with a detectable trait, the cellular product selected from the group consisting of a foreign protein and a negative strand RNA.

2. Cotton plants germinated from the seeds of claim 1.

3. Cotton seeds as claimed in claim 1 wherein the foreign gene codes for the production of a negative strand RNA effective to condition a somatic change to the cotton plant.

4. Cotton seeds as claimed in claim 1 wherein the promoter sequence is selected from the group consisting of the nopaline synthase promoter from Agrobacterium tumefaciens and the cauliflower mosaic virus 35s promoter.

5. A cotton plant comprising in the genome of at least some of its cells a foreign gene construction including promoter and control sequences effective in cotton cells, said gene construction further including a heterologous coding sequence, the foreign gene

² This appeal is related to an appeal in the Merged Reexamination proceeding for U.S. Patent 5,004,863 (Reexamination Control Nos. 90/003,298 and 90/003,452; Appeal No. 1997-1547). The two appeals were jointly heard on July 14, 1997.

Appeal No. 1997-1546

construction effective to cause expression of a detectable cellular product coded by the heterologous coding sequence in the plant cells, the cellular product selected from the group consisting of a foreign protein and a negative strand RNA.

6. A cotton plant comprising in its genome at least two foreign gene constructions each including promoter and control sequences effective in cotton cells, both gene constructions further including heterologous coding sequences, both foreign gene constructions effective to cause the expression of a detectable cellular product coded by the heterologous coding sequence in the plant cells, the cellular product of one of the foreign gene constructions selected from the group consisting of a foreign protein and a negative strand RNA, the other foreign gene construction being a selectable marker gene which imbues the cotton cells with the trait of resistance to a selection agent.

7. A cotton plant comprising in its genome at least two foreign gene constructions each including promoter and control sequences effective in cotton cells, both gene constructions further including heterologous coding sequences, both foreign gene constructions effective to cause the expression of a detectable cellular product coded by the heterologous coding sequence in the plant cells, the cellular product of one of the foreign gene constructions selected from the group consisting of a foreign protein and a negative strand RNA, the other foreign gene construction being a selectable marker gene which imbues the cotton cells with the trait of resistance to a selection agent, the foreign gene constructions having been transformed into the cotton plant or the progenitors of the cotton plant by *Agrobacterium*-mediated plant transformation.

The references relied on by the examiner are:

Eur. Pat. App. 142,924 (Adang III)

May 29, 1985

Zhou et al. (Zhou 1983), "Introduction of Exogenous DNA into Cotton Embryos," Methods in Enzymology, Vol. 101, pp. 433-481, 1983.

Appeal No. 1997-1546

Jian et al. (Jian), "A Molecular Demonstration of the Introduction into Cotton Embryos of Exogenous DNA," Acta Biochimica et Biophysica Sinica, Vol. 16, No. 3, pp. 325-327, 1984.

Zhou (Zhou 1986), "Genetic Manipulation of the Ovule After Pollination," Chapter 19 in Experimental Manipulation of Ovule Tissues, Chapman et al. (Eds.), Longman, New York, pp. 240-250, 1986.

The references discussed by the merits panel are:

Adang et al. (Adang I), "Insect Resistant Plants," Chemical Abstracts, Vol. 103, No. 9, Abstract No. 66080c, 1985.

Eur. Pat App. 142,924 (Adang II), pages 1, 22 and 77 only. May 29, 1985

There are three rejections pending in this merged reexamination proceeding:

1. Claims 1, 2 and 5 under 35 U.S.C. § 102(b) as anticipated by Zhou 1986;
2. Claims 1, 2 and 5 under 35 U.S.C. § 102(b) as anticipated by Zhou 1983 in light of either Jian or Zhou 1986; and
3. Claims 1-7 under 35 U.S.C. § 103 as unpatentable over Adang III taken with Zhou 1983 and either Jian or Zhou 1986.

We reverse.

PRELIMINARY MATTERS

The provisions for reexamination of issued patents are set forth in 35 U.S.C. §§ 301-306. Section 303 provides in pertinent part:

- (a) Within three months following the filing of a request for reexamination under the provisions of section 302 of this title, the Commissioner will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request . . . (emphasis added)

Appeal No. 1997-1546

During the July 14, 1997 hearing of this and related appeal 1997-1547, patent owner Monsanto Company raised the question of whether the decision in In re Portola Packaging Inc., 110 F.3d 786, 42 USPQ2d 1295 (Fed. Cir. 1997), was implicated in the two merged reexamination proceedings on appeal. Our first consideration, therefore, is whether the issues in this reexamination have been previously considered and resolved.

In interpreting the statutory phrase “a substantial new question of patentability,” the court in Portola Packaging noted that Congress, through the reexamination statute, authorized the PTO to reexamine an issued patent “within strictly defined limits.” Specifically, “reexamination was intended only for those instances in which the examiner did not have all of the relevant prior art at his disposal when he originally considered the patentability of an invention.” In re Portola Packaging Inc., 110 F.3d 786, 789-90, 42 USPQ2d 1295, 1298-99 (Fed. Cir. 1997). The court held that “a rejection made during reexamination does not raise a substantial new question of patentability if it is supported only by prior art previously considered by the PTO in relation to the same or broader claims.” Id. 110 F.3d at 791, 42 USPQ2d at 1300.

After considering appellant’s oral argument, we agreed that Portola Packaging was fairly implicated, and remanded this reexamination proceeding to the examiner to determine exactly which references or portions of references were relied on during the prosecution of the ‘135 patent, to consider the issues raised by the decision in Portola Packaging, and to take appropriate action (Paper No. 51 in 90/003,297 and Paper No. 49 in 90/003,453). The examiner’s position has not changed and we have before us now the

Appeal No. 1997-1546

examiner's Response to the Remand (Paper No. 47 in 90/003,297 and Paper No. 45 in 90/003,453) and appellant's Comments on the Examiner's Response to the Remand (Paper No. 49 in 90/003,297 and Paper No. 47 in 90/003,453). We have taken the respective positions of the examiner and patent owner into account in reaching our decision.

We hold that each of the rejections before us is based, in whole or in part, on prior art not before the examiner during earlier prosecution, and so each is based on a substantial new question of patentability. We set forth the following sequence of events in support of our conclusion:

Prosecution History

Applications. 06/937,384 and 07/575,035

The present application, application 07/575,035, is a continuation of application 06/937,384, filed December 3, 1986. The record of the parent application was considered during the prosecution of the present application, as indicated by the examiner in the search notes dated April 18, 1991. The first action on the merits in 06/937,384 (Paper No. 6, February 3, 1988), included a rejection of certain claims over Adang I. In responding to the rejection (Paper No. 7, August 15, 1988), applicant indicated that Adang I was based on Eur. Pat. App. 142,924, and supplied excerpts from the patent (Adang II). The Information Disclosure Statement (Form PTO-1449) which accompanied Paper No. 7 listed the patent without indicating which portions were supplied. By oversight or otherwise, the citation was not initialed by the examiner. Nevertheless, it appears from the

Appeal No. 1997-1546

record that the title page (which included an abstract), and pages 22 and 77 of Eur. Pat. App. 142,924 were before the examiner during the examination procedure of the parent application (page 7, Paper No. 7). Zhou 1983 was also submitted with applicant's response and discussed briefly (page 3, Paper No. 7); the citation of this reference on the Form PTO 1449 was initialed by the examiner. Zhou 1983 was resubmitted with an Information Disclosure Statement which accompanied Paper No. 15 in application 07/575,035; its citation on the PTO-1449 was also initialed by the examiner.

Merged Reexamination Requests 90/003,297 and 90/003,453

There are three rejections pending in this merged proceeding. According to the examiner, claims 1, 2 and 5 are anticipated by Zhou 1986; and also by Zhou 1983 in light of Zhou 1986 or Jian. In addition, claims 1 through 7 of the '135 patent stand rejected as unpatentable over Adang III³ taken with Zhou 1983 and either Zhou 1986 or Jian. Neither Adang III, Zhou 1986 nor Jian was considered with respect to the patented claims prior to this merged reexamination proceeding; each of the rejections is based on a substantial new question of patentability and is properly before us for review.

³ We invite attention to the detailed discussion of Adang I, II and III in the opinion handed down on even date in related appeal 1997-1547.

THE EXAMINER'S REJECTIONS

The patented claims are directed to genetically modified cotton seeds and plants, each transformed with a “chimeric recombinant gene construction” or a “foreign gene construction” including a foreign gene and promoter and control sequences operable in cotton, so that the foreign gene is expressed in the plants as a protein or a negative strand RNA molecule. Claim 5 additionally requires that the gene construction includes a heterologous coding sequence, and claims 6 and 7 require that the construction includes a “selectable marker gene which imbues the cotton cells with the trait of resistance to a selection agent.” Finally, claim 7 requires that the modified plants are produced through Agrobacterium-mediated transformation. There are three rejections pending in this merged reexamination proceeding.

According to the examiner, claims 1, 2 and 5 are anticipated by Zhou 1986, and also by Zhou 1983 in light of either Zhou 1986 or Jian. We will treat the two rejections together, as Zhou 1986 and Zhou 1983 have similar disclosures, and are relied on in the same manner.

Both Zhou 1986 and Zhou 1983 disclose the results of attempts to produce transformed cotton plants by injecting fragmented donor cotton plant DNA into flowering recipient cotton plants. Ripened seeds were planted and offspring obtained, many of which resembled the donor plant in certain respects. Some of the plants grown from the seeds of the offspring maintained a resemblance to the donor plant.

Appeal No. 1997-1546

“The name of the game is the claim,” In re Hiniker Co., 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998). In making a patentability determination “[a]nalysis begins with a key legal question -- what is the invention claimed?” since “[c]laim interpretation . . . will normally control the remainder of the decisional process,” Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1567-68, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987). In the present case, claims 1 and 2 are directed to cotton seeds or plants, each of which comprises, as part of its genome, “a chimeric recombinant gene construction.” Claim 5 is directed to a cotton plant comprising, as part of its genome, “a foreign gene construction.”

Emphasizing that the claims “specify what the plant genome contains -- not what was inserted,” the examiner maintains that Zhou’s DNA fragments “upon integration into the cotton plant genome formed chimeric recombinant gene constructions” because “[t]he DNA fragments are gene constructs and the recombinant joining of a DNA fragment to flanking DNA with which it is not naturally associated . . . produced a chimeric recombinant gene construction” (emphasis added). See pages 12 and 13 of the Answer.

Having carefully considered the examiner’s and patent owner’s positions, we agree with patent owner that the examiner has failed to establish that Zhou’s fragmented DNA would be considered a “construction” by those skilled in the art, as the word appears throughout the specification and in the phrases “chimeric recombinant gene construction” and “foreign gene construction.” Rather, the use of the word in the specification and patented claims is entirely consistent with the interpretation urged by patent owner (page

Appeal No. 1997-1546

33 of the Brief). That is, “gene construction,” as used in the patented claims, “would be understood by workers in this art [to] be a gene that has been manipulated . . . to join together regions of genes . . . that are not found together in nature,” quite apart from its insertion into the cotton genome.

Thus, the genome of a cotton seed or plant meeting the limitations of the patented claims has two sites, one at each end of the inserted donor DNA, where donor and recipient DNA molecules are joined in an artificial arrangement, plus at least one site, within the inserted donor DNA, where stretches of DNA not found together in nature are artificially joined. Cotton transformed by fragmented DNA according to Zhou 1986 or Zhou 1983, would have only two non-natural sites (one at each end of an inserted fragment), and therefore, cannot anticipate the claimed cotton seeds or plants. Accordingly, both rejections of claims 1, 2 and 5 under 35 U.S.C. § 102(b) are reversed.

In addition, claims 1 through 7 stand rejected under 35 U.S.C. § 103 as unpatentable over Adang III taken with Zhou 1983 and either Zhou 1986 or Jian. The examiner’s rejection of the claims is premised on a combination of Adang III and Zhou 1983. Zhou 1986 and Jian were cited to reinforce the teachings of Zhou 1983.

Adang III is principally directed to Agrobacterium Ti plasmid-mediated transformation of plants with genes encoding insecticidal structural proteins. The working examples demonstrate transformation of tobacco with a Bacillus thuringiensis gene encoding the insecticidal crystal protein, *-endotoxin (Bt toxin), and insertion of insecticidal

Appeal No. 1997-1546

genes into other plants, including cotton, is suggested. At page 33, the reference briefly mentions other vectors and methods of delivering them:

Although the preferred embodiment of this invention incorporates a T-DNA-based *Agrobacterium*-mediated system for incorporation of the insecticide gene into the genome of the plant which is to be made insect resistant, other means for transferring and incorporating the gene are also included within the scope of this invention. Other means for the stable incorporation of the insecticide gene into a plant genome additionally include, but are not limited to, use of vectors based upon viral genomes, minichromosomes, transposons, and homologous or nonhomologous recombination into plant chromosomes. Alternate forms of delivery of these vectors into a plant cell additionally include, but are not limited to, direct uptake of nucleic acid, fusion with vector-containing liposomes, microinjection, and encapsidation in viral coat protein followed by an infection-like process.

In describing Adang III (at page 5 of the Answer), the examiner initially mentions “the insertion of foreign DNA encoding Bt toxin . . . , and a selectable marker gene” by *Agrobacterium* Ti plasmid-mediated transformation, but immediately shifts the focus of the discussion to the portion of the reference quoted above, implicitly excluding *Agrobacterium* Ti plasmid-mediated transformation of plants from the rejection:

Although Adang et al described *Agrobacterium* mediated transfer of T-DNA at length, other means of stably incorporating the foreign insecticidal gene were said to be known for delivering the vector to the plant cell and that these alternative means included direct DNA uptake and microinjection (page 33).

This shift in focus appears to be crucial to the rejection, because the examiner relies on the “other means of stably incorporating the foreign insecticidal gene” to establish a link to the secondary reference, Zhou 1983.

Appeal No. 1997-1546

Zhou 1983 discloses the results of attempts to produce transformed cotton plants by injecting donor cotton plant DNA into the axile placentae of flowering recipient cotton plants. Seeds ripened from the flowers were planted and offspring obtained, many of which resembled the donor plant in certain respects. Some of the plants grown from the seeds of the offspring maintained a resemblance to the donor plant.

According to the examiner's statement of the rejection:

Adang et al provided the foreign DNA construction and the motivation to integrate that foreign DNA into the cotton genome by any available means; the secondary references provided an available means of how to put the foreign DNA into cotton. At the time this invention was made it would have been obvious to one of ordinary skill in the art to modify the primary reference with the teachings of the secondary references in order to insert the DNA encoding Bt toxin protein into cotton plants so as to make the cotton plants resistant to insect predation . . .

The proposed manner of combining the references leaves a great deal to conjecture. From the examiner's description of Adang III and nebulous statement of the rejection, we infer that the examiner concluded that it would have been obvious for one skilled in the art to transform cotton with Adang III's "foreign DNA construction" by an "alternative means," such as that taught by Zhou 1983, as each reference either discusses or discloses transformation of cotton by direct injection of DNA.

We shall not pass on whether this would be an adequate basis for combining Adang III and Zhou 1983 if both references mentioned direct injection in the same context or environment; the fact is, they do not. Adang III suggests direct injection or microinjection of non-gametic cotton cells in tissue culture with foreign, heterologous DNA (bacterial

Appeal No. 1997-1546

genes encoding insecticidal proteins), while Zhou 1983 discloses direct injection of fragmented DNA (from a donor cotton plant) into the egg cells and/or zygotes of a just-fertilized mature cotton plant.

Viewing each reference in its entirety, the link between the two is illusory. At best, the references describe parallel approaches to transforming cotton. Taking a step back, we cannot agree that the references lend themselves to the proposed combination and we see no reason, other than hindsight based on the disclosure of the '135 patent, to modify Adang III to arrive at the claimed invention. In our judgment, the combined disclosures of the references are insufficient to reach the subject matter on appeal.

Moreover, in addition to a foreign gene (e.g., Adang III's insecticide gene), claims 6 and 7 require a "selectable marker gene which imbues the cotton cells with the trait of resistance to a selection agent." The statement of the rejection does not specify what is included in the "foreign DNA construction," but the portion of Adang III relied on in the rejection concerns "stable incorporation of the insecticide gene." Even if that portion of Adang III mentioned a selection resistance gene, it would have no purpose or function in Zhou 1983's method, as Zhou 1983 teaches "regeneration of a plant through exogenous DNA directly introduced into the embryos of a living plant" and breeding "disease-resistant plant[s] by growing the [zero generation] seeds directly in a field, or select[ing] resistances to environmental factors by growing the seeds under specified conditions." See the paragraph bridging pages 441 and 442 of Zhou 1983. The examiner has proposed no reason why one skilled in the art would incorporate the required "selection agent

Appeal No. 1997-1546

resistance gene” in a “foreign DNA construction” to be introduced into cotton by a process that deliberately avoids selection in tissue culture.

35 U.S.C. § 103 requires that obviousness be determined on the basis of the claimed “subject matter as a whole.” Where, as here, the determination of obviousness is based on less than the entire claimed subject matter, the examiner’s conclusion of obviousness is unsound and cannot be maintained.

Accordingly, the rejection of claims 1 through 7 under 35 U.S.C. § 103 is reversed.

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

REVERSED

Appeal No. 1997-1546

Sherman D. Winters
Administrative Patent Judge

William F. Smith
Administrative Patent Judge

Teddy S. Gron
Administrative Patent Judge

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Appeal No. 1997-1546

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