

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DENNIS E. McCABE and BRIAN J. MARTINELL

Appeal No. 97-0480
Application No. 07/858,818¹

ON BRIEF

Before WINTERS, GRON, and SPIEGEL, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

¹ Application for patent filed March 27, 1992. According to appellants, this application is a division of Application 07/422,921, filed October 17, 1989, now U.S. Patent 5,120,657, issued June 09, 1992, which is a continuation-in-part of Application 06/938,570, filed December 05, 1986, now abandoned, and a continuation-in-part of Application 07/193,357, filed May 12, 1988, now U.S. Patent 5,015,580, issued May 14, 1991, which is a continuation-in-part of Application 07/079,658, filed July 29, 1987, now abandoned.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the decision of the examiner refusing to allow claims 10, 13, 14 and 16 as amended subsequent to the final rejection, which are all of the claims pending in this application.² Claim 10 is illustrative:

10. A method of delivering genes into the cells of a plant comprising the steps of:

- preparing copies of an expression vector appropriate for the plant including an exogenous coding region and flanking regulatory sequences effective to express the coding region in the cells of the plant;
- coating the copies of the expression vector onto biologically inert carrier particles;
- applying the coated carrier particles in a layer on a biologically inert carrier sheet;
- placing the carrier sheet above a pair of spaced electrodes which have a gap between them bridged by a water droplet;
- mounting a retaining screen spaced above the carrier sheet for retaining the carrier sheet after a selected upward distance of travel;
- placing on a target surface above the retaining screen cells of the plant; and
- applying an electric voltage between the electrodes sufficient to generate an electric discharge between the electrodes vaporizing the water droplet, the shock wave from which accelerates the carrier sheet toward the retaining screen which retains the carrier sheet permitting the carrier particles to continue on to penetrate the cells of the plant, the force of the penetration being controlled by the voltage of the electric discharge.

The examiner relies upon the following references as evidence of obviousness:

² Claims 15, 26 and 27 were cancelled and claim 10 was amended by the Amendment filed April 10, 1995 (Paper no. 16) which was approved by the examiner in the Advisory Action mailed May 05, 1995 (Paper no. 18). Claim 17 was cancelled and claims 10 and 16 were further amended by the Amendment filed September 07, 1995 (Paper no. 22) which was approved by the examiner in the Advisory Action mailed November 15, 1995 (Paper no. 24).

Appeal No. 97-0480
Application No. 07/858,818

Sanford et al. (Sanford) 4,945,050 Jul.31, 1990
(filed Nov. 13, 1984)

Klein et al. (Klein), *Program and Abstracts for an International Symposium Biotechnology in Plant Science: Relevance to Agriculture in the Eighties*, "Particle Gun Technology: A Novel Method for the Introduction of DNA into Living Cells," organized by the Cornell University Biotechnology Program, Ithaca, NY, June 23-27, 1985, Poster #28.

Sanford et al., (Sanford "R"), "Delivery of Substances into Cells and Tissues Using a Particle Bombardment Process," *5 Particulate Science and Technology*, 1987: 27-37).³

Appellants' claimed invention is directed to a method of introducing cloned genes into living plant cells by physically bombarding the cells with accelerated DNA-coated carrier particles. The DNA-coated carrier particles are placed on a carrier sheet which is then placed above a pair of spaced electrodes having a gap therebetween bridged by a water droplet. A retaining screen is placed a selected distance above the carrier sheet. The cells are placed on a target surface a selected distance above the retaining screen. Electric voltage is applied to the electrodes to create an electric discharge which vaporizes the water droplet, thereby releasing energy, i.e., producing a shock wave. The released energy impacts and accelerates the carrier sheet until it is stopped by the retaining screen whereupon the carrier particles leave the carrier sheet, pass through the screen and continue on penetrate the target cells. According to appellants, accelerating a planar carrier sheet coated with evenly distributed carrier particles towards the target surface allows the carrier particles to impact the

³ We note that the examiner did not include the Sanford "R" reference in her list of the prior art of record on page 3 of the Answer.

Appeal No. 97-0480
Application No. 07/858,818

cells in the same linear direction with suitable force and frequency to provide a predictable and uniform delivery of carrier particles.

(Brief pages 3-4 and 9-10.)

*ISSUES*⁴

I. Claims 10, 13, 14 and 16 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sanford taken with Klein.

II. Claims 10, 13, 14 and 16 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9-16, 19, 21-24, 37-40 and 42 of copending application no. 07/931,882 in view of Sanford "R."

⁴ The examiner has withdrawn (a) the provisional obviousness-type double patenting rejections of claims 10, 13-17, 26 and 27 (now claims 10, 13, 14 and 16) over (i) claims 1-20, 22 and 23 of copending Application 07/485,111, (ii) claims 1-7, 9 and 10 of copending Application 08/701,416, (iii) claims 1-4, 6-8, 11-14 and 16-18 of copending Application 07/670,610, and (iv) claims 1-10 and 19 of copending Application 07/910,470 as set forth in the final Office action mailed October 05, 1994 (Paper no. 14) in view of the abandonment of the copending applications (Answer, pages 4-5) and (b) the rejection of claims 10, 13-17, 26 and 27 (now claims 10, 13, 14 and 16) under 35 U.S.C. § 112, first paragraph, as enabled only for delivery to plant cells as set forth in the final Office action mailed October 05, 1994 (Paper no. 14) in view of the cancellation and/or amendment of these claims (Answer, page 5).

III. Claims 10, 13, 14 and 16 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9-16, 19, 21-24, 37-40 and 42 of copending application no. 07/931,882 in view of Sanford.

For reasons *infra*, we will reverse rejections I and II and affirm rejection III.

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's answer (Paper no. 27, mailed June 07, 1996) for the examiner's complete reasoning in support of the rejections, and to the appellants' brief (revised) (Paper no. 26, filed December 11, 1995) for the appellants' arguments.

Appellants state the claims "stand or fall together as a single group" (Brief, page 6). We therefore limit our discussion to claim 10. 37 C.F.R. § 1.192(c)(5)(1994).

OPINION

I. Rejection of claims 10, 13, 14 and 16 under 35 U.S.C. § 103 as being unpatentable over Sanford taken with Klein.

a. Claim interpretation

During *ex parte* prosecution, claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Unless otherwise defined by applicant in the specification, claim language should be read in light of the specification as it would be interpreted by those of ordinary

skill in the art. *In re Sneed*, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983). According to the specification, a carrier sheet is formed of flexible biologically inert sheet material, e.g., 1 mil (i.e., 0.025 mm) or, preferably, 0.5 mil (i.e., 0.0127 mm) plastic coated aluminized mylar sheet sized 9 by 11 millimeters (page 8, lines 15-35). In other words, the carrier sheet is a planar structure. The carrier sheet functions to arrange the pattern of carrier particles as they contact the target surface (sentence bridging pages 8-9). Carrier particles are not simply dusted onto the carrier sheet in an uneven manner, but are applied so as to form a uniform and reproducible layer of carrier particles to ensure that as many cells on the target surface as possible are impacted (page 9, lines 1-4; page 15, lines 17-35). Therefore, when reading the claims in light of the specification, we interpret a biologically inert “carrier sheet” as a biologically inert *planar* carrier sheet and “applying” the coated carrier particles in a layer on a biologically inert “carrier sheet” to mean *evenly distributing* the coated carrier particles in a layer on a biologically inert *planar* carrier sheet.

b. Statement of rejection

Sanford describes physically accelerating particles, which may be coated or impregnated with biological substances, e.g., DNA and RNA, at living cells at a speed whereby the particles penetrate the surface of the cells and become incorporated into the cells (col. 3, lines 17-38; col. 7, lines 8-13). Particles may be accelerated to high velocities (2a) by a shot of compressed gas blast, (2b) by translating the kinetic energy of a bullet-sized macroprojectile hitting one side of a blast plate to

particles on the other side of the plate, (2c) by stopping a fired macroprojectile bullet, which contains particles in a forward cavity thereof, with a device which allows the particles to pass through and continue ahead at full speed, (2d) by allowing particles attached to or dispersed on the perimeter of a high speed rotor to escape tangentially therefrom, or (2e) by electrostatically accelerating charged particles (Figs. 2a-2e; col. 4, lines 20-38). Generally, the particles should be small enough to produce minimal cell damage and large enough to acquire sufficient momentum to penetrate the cell; momentum being a function of size, density and velocity, with sufficient integrity to withstand the physical forces inherent in the process (col. 5, lines 38-66). Exemplary particles include inert particles, e.g., gold or tungsten spheres (col. 6, lines 39-44) and subject cells include plant pollen and plant protoplasts (col. 7, lines 27-31). Examples 1 and 3 show delivery of tungsten spheres into onion epidermal cells using a shot of compressed gas blast (Fig. 7; col. 7, line 49 - col. 8, line 27; col. 11, line 10 - col. 12, line 3) and macroprojectile "bullet" acceleration of particles (Figs. 2b and 2c; Fig. 8; col. 8, line 52 - col. 9, line 2; col. 12, lines 22-53), respectively.

According to the examiner, Sanford "would have anticipated the invention but for the fact that the particles delivered to the onion epidermal cells were not coated with DNA" (Answer, page 8, first paragraph). The examiner relies on Klein to show ballistic acceleration of DNA-coated particles into onion epidermal cells and concludes that it would have been obvious to one of ordinary skill in the art to

modify Sanford with the teachings of Klein to deliver DNA-coated particles to plant cells with a reasonable expectation of success (Answer, pages 5, 7 and 8).

However, at least one other difference between Sanford and the claimed invention is implicitly acknowledged by the examiner, i.e., use of an electric discharge induced “shock wave” to accelerate the particles off the coated carrier sheet. At page 5 of the Answer, the examiner opines that use of an electric discharge induced shock wave as an acceleration means would have been a routine matter of design choice.

c. Analysis

To establish a *prima facie* case of obviousness, there must be both some suggestion or motivation to modify the reference or combine reference teachings and a reasonable expectation of success. Furthermore, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

The examiner relies on Sanford’s Example 3, Figs. 2b, 2c, 8a and 8b, to show acceleration of particles from a flat surface which was stopped by a retaining screen which allowed the unrestrained particles to continue forward into the target and an apparatus therefore (Answer, page 7). The examiner equates the macroprojectile of Figs. 8a, 8b and 12 and the stopping plate/means in Figs. 8a and 12 in Sanford with the recited moveable carrier sheet and retaining screen, respectively (Answer, page 10).

However, assuming *arguendo*, that the single aperture stopping plate/means did equate to a retaining screen, we agree with appellants that the solid, bullet shaped macroprojectile of Figs. 2c, 8a, 8b and 12 cannot be fairly characterized as a carrier sheet as that term would be interpreted by one of ordinary skill in the art when read in light of the specification, even though both the macroprojectile and the carrier sheet have a “flat surface.” We also agree with appellants that impacting and deforming the particle-coated 0.8 mm copper plate of Fig. 2b does not meet the claimed limitation of accelerating a carrier sheet forward towards a retaining screen. (Brief, pages 12-14).

Furthermore, although the two modifications, i.e., Figs. 2b and 2c, discussed in Example 3 are based upon the same concept of “mounting the small particles on a larger particle or surface, accelerating the larger body by impact or ballistic means, and then stopping the larger body, while allowing the smaller particles to maintain their velocity” (col. 12, lines 27-32), the examiner has failed to explain how and why the skilled artisan would have selected, modified and/or combined various portions of these two modifications to obtain appellants’ claimed invention. For example, the copper plate of Fig. 2b performs the same function of stopping the macroprojectile bullet as the stopping plate/means in Fig. 2c does. The examiner has failed to explain why the skilled artisan would have used a *movable* carrier sheet as stopping means/plate, especially since a moveable “blast” plate/carrier sheet would appear to be less efficient in translating the kinetic energy of the impacting macroprojectile bullet to smaller particles on its surface, thereby diminishing the effective velocity and penetration of the

Appeal No. 97-0480
Application No. 07/858,818

particles. We agree with appellants that nothing in Klein makes up for the deficiencies in Sanford (Brief, page 11). We also agree with appellants that selection of an appropriate force to accelerate a layer of particles on carrier sheet, e.g., an electric discharge-induced shock wave, depends upon selecting a carrier sheet as the “larger body” in Sanford to begin with (Brief, pages 16-17).

Therefore, we conclude that the examiner has not established a *prima facie* case of obviousness as to the claimed invention which requires a movable carrier sheet.

With regard to the discussion of unexpected results presented in the McCabe Declaration executed November 13, 1991, and submitted with the response (Paper no. 7) filed January 7, 1993 (Brief, pages 18-21), having concluded that the examiner has not established a *prima facie* case of obviousness from the teachings of the prior art, we need not reach the sufficiency of this rebuttal evidence.

II. Provisional rejection of claims 10, 13, 14 and 16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9-16, 19, 21-24, 37-40 and 42 of copending application no. 07/931,882 in view of Sanford “R.”

According to appellants, since all of the claimed subject matter is entitled to an effective filing date of December 05, 1986 (based upon a priority claim to USSN 06/938,570 under 35 U.S.C. § 120 which the examiner acknowledged in the final Office action mailed

Appeal No. 97-0480
Application No. 07/858,818

October 05, 1995 (Paper no. 14, page 2)), the 1987 Sanford “R” reference is not available as prior art (Brief, page 6). Since the examiner has not challenged appellants’ statements, we find that Sanford “R” is not available as prior art and reverse the provisional rejection of claims 10, 13, 14 and 16 under the judicially created doctrine of obviousness-type double patenting over the claims of the ‘882 application in view of Sanford “R.”

III. Provisional rejection of claims 10, 13, 14 and 16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9-16, 19, 21-24, 37-40 and 42 of copending application no. 07/931,882 in view of Sanford.

Appellants have not challenged the propriety of the provisional rejection of claims 10, 13, 14 and 16 under the judicially created doctrine of obviousness-type double patenting over the claims of the ‘882 application in view of Sanford and are prepared to file a Terminal Disclaimer in either application should the other issue as a patent (Brief, page 6; Response filed July 11, 1994 (Paper no. 13), page 3). Since no Terminal Disclaimer has yet been submitted to overcome this rejection, we summarily affirm the provisional rejection of claims 10, 13, 14 and 16 under the judicially created doctrine of obviousness-type double patenting over the claims of the ‘882 application in view of Sanford.

CONCLUSION

In conclusion, the decision of the examiner (I) to reject claims 10, 13, 14 and 16 under 35 U.S.C. § 103 as being unpatentable over Sanford taken with Klein is **reversed**, (II) to provisionally

Appeal No. 97-0480
Application No. 07/858,818

