

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* JAMES E. HAGSTROM, MARK NOBLE, JULIA HEGGE, and  
VLADIMIR G. BUDKER

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Appeal 2008-1909  
Application 10/680,742  
Technology Center 1600

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Decided: March 13, 2008

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Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES,  
*Administrative Patent Judges.*

SCHEINER, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims 1, 2, and 4-14, directed to a method of delivering DNA to a prostate cell *in vivo*, which the Examiner has rejected as nonenabled. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

## BACKGROUND

“The purposeful delivery of genetic material to somatic cells for the purpose of treating disease or for biomedical investigation has been termed gene therapy.” (Spec. 1: 11-12.) “A basic challenge for biotechnology is to develop approaches for delivering genetic information to cells *in vivo*.” (Spec. 1: 10-11.) “To be successful, the [genetic material] must be delivered to a therapeutically significant percentage of the affected cells in a manner that is both efficient and safe.” (Spec. 1: 14-16.)

“[T]he development of methods for gene transfer into the prostate is attractive given that prostate cancer is a leading cause of morbidity and mortality in men and has a stronger hereditary component than any other type of cancer.” (Spec. 1: 20-22.) “[G]ene therapy could offer a new tool in the battle against this cancer.” (Spec. 1: 24-25.) “Delivery of genes to prostate in animal models will also further biomedical research into the causes, mechanisms and potential treatments of enlarged prostate, prostate cancer and benign prostatic hyperplasia.” (Spec. 1: 25-27.)

“Most prostate tumors arise from the secretory epithelial cells that line the luminal surface of the prostatic ducts and acini.” (Spec. 1: 22-24.) “[T]he present invention provides processes for *in vivo* delivery of polynucleotides to prostate cells in a mammal comprising: injecting a solution containing the polynucleotide into a vessel of the prostate . . . [and] increasing permeability of [the] prostate vessels . . . to provide for delivery of the polynucleotides to . . . prostate cells outside the vessel.” (Spec. 2: 12-17.)

The Specification provides several working examples demonstrating intravascular delivery of DNA to prostate cells in mice, rats, and monkeys, and subsequent expression of that DNA in the extravascular prostate tissue. (Spec. 21-29.)

## DISCUSSION

### *CLAIMS*

Claims 1, 2, and 4-14 are pending and on appeal. Claim 1 is representative and reads as follows:

1. A process for delivering DNA to a prostate cell in a mammal comprising:
  - a) inserting a delivery device into a lumen of an afferent or efferent vessel of the prostate;
  - b) injecting a solution containing the DNA into the lumen of the vessel;
  - c) increasing permeability of the vessel to the DNA;
  - d) delivering the DNA to the prostate cell outside of the vessel; and,
  - e) expressing the DNA.

### *ENABLEMENT*

Claims 1, 2, and 4-14 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled, on the basis that “the only intended use of the claimed invention is a method of gene therapy to treat disease, specifically, prostate cancer” (Ans. 4-5), but “the instant specification fails to teach or address the limitations that encompass the treatment of any disease using gene therapy” (Ans. 7).

Appellants argue that they “have claimed a process of delivery and expression in mammals and no more” (Br. 9), and “have supported the claims with numerous examples in the specification showing delivery and

expression to mice, rats and monkeys” (*id.*), and “only reasonable adjustments to volume and pressure need be made for the process of delivering and expressing DNA to be applicable to any mammal” (*id.*).

The Examiner acknowledges that “no treatment is specified in the base claim” (Ans. 4), and that the Specification’s working examples demonstrate “that a polynucleotide can be delivered to a prostate cell in a mammal using the claimed process” (Ans. 7). Nevertheless, the Examiner contends that the claims “read[ ] on gene therapy because the claimed process results in the expression of an exogenous polynucleotide in a target mammal” (Ans. 4), and the “claims are examined in view of the intended use . . . , which is gene therapy” (Ans. 7).

In this regard, the Examiner cites several references<sup>1</sup> as support for his position that “the field of gene therapy is unpredictable” and “successful implementation of gene therapy protocols was not routinely obtainable by those skilled in the art” (Ans. 5.), “[a]t the time the invention was made” (*id.*).

Appellants argue that their Specification provides “other expressly stated uses” for the claimed method (Br. 8), including “[d]elivery of genes to prostate in animal models . . . [to] further biomedical research into the causes, mechanisms and potential treatments of enlarged prostate, prostate

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<sup>1</sup> Manuel A.F.V. Gonçalves, *A Concise Peer Into the Background, Initial Thoughts and Practices of Human Gene Therapy*, 27 BioEssays 506-517 (2005); H. Parekh-Olmedo et al., *Gene Therapy Progress and Prospects: Targeted Gene Repair*, 12 Gene Therapy 639-646 (2005); Inder M. Verma & Matthew D. Weitzman, *Gene Therapy: Twenty-First Century Medicine*, 74 Annual Review of Biochemistry 711-738 (2005).

cancer and benign prostatic[ ]hyperplasia” (*id.*). Appellants argue that their process “could be used in research toward a therapy or as a part of a therapeutic treatment developed by another” (Br. 9), and they “do not have to prove that a correlation exists between a particular activity and an asserted therapeutic use [or in this case a non-asserted therapeutic use] . . . , nor do they have to provide actual evidence of success in treating humans” (*id.*) (bracketing original).

We agree with Appellants that the Examiner has applied an overly stringent standard for enablement in this case. “[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). “That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is ‘undue.’” *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (emphasis in original). Some experimentation, even a considerable amount, is not “undue” if, for example, the specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

The enablement analysis must be focused on the product or method defined by the claims. “Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.” *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003). *See also In re Cortright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999) (claims to

method of “restoring hair growth” encompassed achieving full head of hair but did not require it).

The claims on appeal are directed to a method of delivering DNA to prostate cells, and expressing the DNA in the cells, not to a method treating prostate disease via gene therapy. It is true that the Specification contemplates the use of the claimed method in gene therapy, but practicing the claimed method does not require a therapeutically effective result.

The Examiner’s apparent position that the Specification cannot teach how to use the claimed method unless it teaches solutions to all the problems in the field of gene therapy is contrary to controlling case law. *See, e.g., In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995).

In *Brana*, the claims were directed to compounds disclosed as anti-cancer agents. *Id.* at 1562. The USPTO rejected the claims as nonenabled, *id.* at 1563-64, despite working examples in Brana’s specification showing treatment of cancer in a mouse model. *Id.* at 1562-63. The USPTO argued that the results of the mouse testing “are not reasonably predictive of the success of the claimed compounds for treating cancer in humans.” *Id.* at 1567. The court concluded that this position “confuses the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption.” *Id.* The *Brana* court held that “[u]sefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans.” *Id.* at 1568.

Here, the claims are simply directed to intravascular delivery of DNA to extravascular prostate cells, and expression of the DNA in the prostate cells, and Appellants' Specification provides several working examples demonstrating just that in mice, rats and monkeys. The Examiner has interpreted the claims as being directed to a method of treating prostate disease via gene therapy, and has discounted the Specification's working examples because they do not describe "the treatment of any disease" in the animals used in the examples (Ans. 7). However, enablement - especially in the context of pharmaceutical inventions - includes an expectation of further research and development. In the pharmaceutical field, an invention can be enabled well before it is ready to be administered to humans. Thus, enablement is not precluded even if the claims encompass methods, such as gene therapy, that have not yet overcome all the obstacles to their clinical use.

The Examiner has not established that undue experimentation would have been required to practice the *claimed* method; specifically, delivering DNA to prostate cells *in vivo*, and expressing that DNA in the prostate cells. The claims do not require therapeutically effective treatment of any disease, and the Examiner erred in concluding that such an effect was required to satisfy 35 U.S.C. § 112, first paragraph.

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SUMMARY

The rejection of claims 1, 2, and 4-14 under 35 U.S.C. § 112, first paragraph, as lacking enablement, is reversed.

REVERSED

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MIRUS CORPORATION  
505 SOUTH ROSA RD  
MADISON WI 53719