

The opinion in support of the decision being entered today is binding precedent of the Trial Section

Paper 39

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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GN,

Junior Party  
(Patent 5,xxx,xxx),

v.

SW,

Senior Party,  
(Application 08/yyy,yyy).

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Patent Interference No. 104,vvv

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Before: McKELVEY, Senior Administrative Patent Judge, and  
SCHAFFER, LEE, TORCZON, GARDNER-LANE and MEDLEY, Administrative  
Patent Judges.

McKELVEY, Senior Administrative Patent Judge

**ORDER DENYING GN PRELIMINARY MOTION 1**

**A. Introduction**

GN Preliminary Motion 1 (Paper 38) seeks to substitute proposed Count A (Paper 38, Appendix A) for Count 1 (Paper 1, page 46), the interference otherwise having been settled. According to GN, the preliminary motion will not be opposed by SW (Paper 38, page 2). In support of the preliminary motion, GN relies, inter alia, on a declaration of Dr. RS (Ex 2008) and a portion of the prosecution history of the SW application (Ex 2002 through Ex 2007) involved in the interference.

**B. Findings of fact**

The record supports the following findings by a preponderance of the evidence.

1. The interference was declared on 10 September 1999 (Paper 1, page 1) with a single count (Paper 1, page 46).
2. Count 1 reads as follows:

Count 1

A method according to claims 1 or 12 of U.S. Patent 5,xxx,xxx (GN),

or

a method according to claims 14 or 16 of application 08/yyyy,yyy (SW),

or

a composition of matter according to claims 20 or 32 of  
GN,

or

a composition of matter according to claims 13 or 15 of  
SW.

3. Claim 1 of the GN patent (Ex 2001) involved in the  
interference reads (**bold** added):

GN claim 1

A method \*\*\* comprising \*\*\* providing \*\*\* a **first  
virion-free nucleic acid construct** \*\*\* and \*\*\* a **second  
virion-free nucleic acid construct** \*\*\*.

4. GN dependent claims 3 and 4 read (bold added):

GN claim 3

The method of claim 1, wherein said first nucleic acid  
construct and said second nucleic acid construct are present  
on the **same** vector.

GN claim 4

The method of claim 1, wherein said first nucleic acid  
construct and said second nucleic acid construct are present  
on **different** vectors.

5. Claim 20 of the GN patent involved in the  
interference reads (**bold** added):

GN claim 20

A [composition of matter] \*\*\* comprising a virion-free **first nucleic acid construct** \*\*\* and \*\*\* a virion-free **second nucleic acid construct** \*\*\*.

6. GN dependent claims 22 and 23 read (**bold** added):

GN claim 22

The mammalian cell of claim 20, wherein said first nucleic acid construct and said second nucleic acid construct are present on the **same** vector.

GN claim 23

The mammalian cell of claim 20, wherein said first nucleic acid construct and said second nucleic acid construct are present on **different** vectors.

7. According to the preliminary motion, the invention claimed by SW is directed only to compositions and methods wherein a first nucleic acid construct and a second nucleic acid construct are present on **different** vectors.

8. The preliminary motion refers to compositions wherein the first nucleic acid construct and the second nucleic acid construct are present on **different** vectors as a "two-component system." These compositions can also be referred to as a two-vector system.

9. Compositions wherein the first nucleic acid construct and the second nucleic acid construct are present on

the **same** vector are referred to in the preliminary motion as a "one-component system." These compositions can also be referred to as a one-vector system.

10. According to the preliminary motion, "the only common subject matter claimed" by both parties is the two-vector system.

11. Further according to the preliminary motion, the subject matter of the GN one-vector claims 3 and 22 is directed to an invention which is said to be separately patentable from the subject matter of the SW two-vector claims.

12. GN therefore moves to have proposed Count A substituted for Count 1.

13. Proposed Count A reads (new material in **bold** and deleted material in brackets and ~~strikeout~~):

Proposed count A

A method according to claims **4** [±] or 12 of U.S. Patent 5,xxx,xxx (GN),

or

a method according to claims 14 or 16 of application 08/yyy,yyy (SW),

or

a composition of matter according to claims **23** [20] or 32 of GN,

or

a composition of matter according to claims 13 or 15 of SW.

14. If GN preliminary motion 1 were to be granted, GN claims 3 and 22 would be designated as not corresponding to Count A.

15. In support of the preliminary motion, GN has filed a declaration of Dr. RS (Ex 2008).

16. Dr. RS is an employee of \*\*\* [the] assignee of the GN patent (Ex 2008, ¶ 1).

17. He holds a Ph.D. in biochemistry, cell and molecular biology from \*\*\* University (Ex 2008, ¶ 2).

18. Dr. RS is not a named inventor (Ex 2008, ¶ 4).

19. Dr. RS states that he has reviewed both the GN patent and the SW application involved in the interference (Ex 2008, ¶ 4).

20. According to Dr. RS, the GN patent describes both a one- and two-vector system, while the SW application describes only a two-vector system (Ex 2008, ¶ 5).

21. Dr. RS tells us (Ex 2008, ¶ 6):

One advantage of the one-vector system, is the need to prepare only one vector. However, a major advantage of the two-vector system is that the rep sequences is [sic--are?] separated from the provirus, thereby minimizing the possibility of integration of the rep gene into the host genome.

22. Dr. RS states the following opinion (Ex 2008, ¶ 7):

I have been asked to consider whether one of ordinary skill in the art, given the one-vector system described [by GN], would be taught that a two vector system would be practicable with a reasonable expectation of success, as of about 1994-1995. At that time, my conclusion is [that] he would not. The proper incorporation, transfection and expression of all necessary information provided in a one vector system could not be reasonably predicted, at that time, to be successfully completed in a two vector system, without experimentation to determine the success of the same. The outcome of those experiments, including determination of whether a suitable two vector system could be prepared, could effectively be used to transfect a eukaryotic host, and then whether the transformat would properly express the heterologous genetic information, could not have been predicted with any reasonable degree of confidence as of 1994.

23. In forwarding the involved GN patent and the SW application files to the board for a determination of whether an interference should be declared, the examiner prepared a statement under 37 CFR § 1.609(b) [Rule 609(b)].

24. In the Rule 609(b) statement, the examiner notes (pages 4-5):

Dependent claims 3, 4, 22, and 23, which recite that the first nucleic acid construct and the second nucleic acid

construct are constructed either on the same vector or on two different vectors, are directed to the same patentable invention disclosed in claims 1-8, and 14-16 of SW et al. because claims 2-8, and 13-16 of SW et al. encompass the presence of two different vectors in the claimed process and/or compositions, e.g., see Example 1 at page 11 of SW et al. Furthermore, it would have been prima facie obvious for one of ordinary skill in the art to have employed one vector comprising two nucleic acid constructs which are ligated directly together, wherein the rep gene product is produced in trans from one nucleic acid construct with respect to the other nucleic acid construct, with a reasonable expectation of success, particularly since nucleic acid vectors that accommodate a large number of inserts or separate nucleic acid constructs that are ligated directly together via appropriate restriction sites are routinely employed in the art, e.g., Berkner, Bio Techniques, Vol. 6, 7, pp. 616-628, 1988, especially column 3 at page 620. Note also that Samulski et al. (WO 94/13788, copy attached) teach that a rep coding sequence can be included in the same plasmid vector that comprises a separate construct expressing an exogenous gene product, e.g., page 12, lines 25-31, Fig. 8).

25. Dr. RS, while mentioning the phrase "one of ordinary skill in the art," fails to state his understanding of the meaning of the phrase.

26. Dr. RS, while testifying that "given the one vector system" one would not be taught that "a two vector system would be practicable with a reasonable expectation of success",

fails to address any other prior art, including, for example, the prior art mentioned in the examiner's Rule 609(b) statement.

27. Dr. RS, while testifying that the "success" of the two-vector system "could not have been predicted with any reasonable degree of confidence as of 1994" does not address (1) the examiner's contrary conclusion or (2) the prior art relied upon by the examiner in support of his conclusion.

### **C. Discussion**

#### 1.

A party filing a motion in an interference, including a preliminary motion, has the burden of proof to show that it is entitled to the relief sought in the motion. 37 CFR § 1.637(a). The burden exists even when the motion is not opposed and the interference otherwise may have been settled. As applied to the facts of this case, GN was under a burden to establish by a preponderance of the evidence that the one-vector invention of GN claims 3 and 22 is directed to an invention which is separately patentable from the two-vector invention claimed by SW. The mere fact that a one-vector system and a two-vector system may not overlap in scope does not per se establish that a one-vector system does not interfere-in-fact with a two-vector system. Aelony v. Arni, 547 F.2d 566, 192 USPQ 486 (CCPA 1977) (an interference-in-fact held to exist between a claim to a method of

using cyclopentadiene and a claim to a method using butadiene, isoprene, dimethylbutadiene, piperylene, anthracene, perylene, furan and sorbic acid; the claims were held to be directed to the same patentable invention even though they did not overlap in scope).

Among other things, GN was under a burden to establish (1) the scope and content of the relevant prior art, (2) any difference between the subject matter of claims 3 and 22 and the prior art and (3) the level of skill in the art. Graham v. John Deere Co., 383 U.S. 1, 17 (1966). For the purpose of the preliminary motion, the SW two-vector system is presumed to be prior art. The presumption is based on the assumption that SW prevails on priority. If SW prevails on priority, then GN would be entitled to claims 3 and 22 only if those claims define an invention which is separately patentable from the subject matter claimed by SW. If GN prevails on priority, it does not matter whether GN one-vector claims 3 and 22 are patentably distinct from any GN two-vector claims, because the GN two-vector claims cannot be prior art vis-a-vis the GN one-vector claims.

In addition, GN was under a burden to establish that given a two-vector system, a person having ordinary skill in the art would not have found the one-vector system to have been prima facie obvious. As part of its case, GN undertook to establish that a person having ordinary skill in the art reasonably would

not have expected success. In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (absolute predictability not required for obviousness--reasonable expectation of success is sufficient).

In ¶ 42 of the NOTICE DECLARING INTERFERENCE (Paper 1, page 32), the parties were instructed as follows:

Affidavits expressing an opinion of an expert must disclose the underlying facts or data upon which the opinion is based. See Fed. R. Evid. 705 and 37 CFR §§ 1.639(b) and 1.671(b).

Opinions expressed without disclosing the underlying facts or data may be given little, or no, weight. See Rohm and Haas Co. v. Brotech Corp., 127 F.3d 1089, 1092, 44 USPQ2d 1459, 1462 (Fed. Cir. 1997) (nothing in the Federal Rules of Evidence or Federal Circuit jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness).

Based on his testimony, we cannot reasonably be sure if Dr. RS understands the meaning of "one of ordinary skill in the art." We generally give no weight to expert testimony on the ultimate issue of obviousness. However, the level of skill in the art is a factual matter and is properly the subject matter of expert testimony. But, unless we know the expert's understanding of the meaning of the phrase "one of ordinary skill in the art," we are not in a very good position to give much weight to the expert's "level of skill in the art" testimony. We need to have

some idea of "What does a person having ordinary skill in the art know?" A carpenter knows how to use a hammer and a saw. What does a person having ordinary skill in the one-vector and two-vector systems know? Dr. RS does not tell us.

Further based on his testimony, we cannot reasonably be sure that Dr. RS was aware of, or considered, any prior art--other than the SW two-vector system--in rendering his opinion. The only prior art which we find discussed in his testimony is the SW two-vector system. Facially, on this record, there is other relevant prior art--that discussed in the examiner's Rule 609(b) statement. On this record, a complete analysis of whether success would have been expected necessarily must be based on all relevant prior art. Since Dr. RS does not mention the prior art cited by the examiner in the Rule 609(b) statement, we decline to credit his testimony with respect to whether one skilled in the art would or would not have expected success. Moreover, we will not undertake to evaluate Dr. RS's opinion vis-a-vis that of the examiner without an analysis by GN.

Dr. RS's testimony does not demonstrate that he was instructed by counsel with respect to the factual standards which are to be used in resolving obviousness issues. For example, we have not been pointed to any evidence that Dr. RS was aware of the prior art cited by the examiner. While a difference between a one-vector system (GN claims 3 and 22) and a two-vector system

(SW claims) is identified by Dr. RS, the prior art cited by the examiner and the level of skill is not discussed.

In the preliminary motion, GN makes reference to, and relies on, part of the prosecution history of the SW application (Ex 2002 through Ex 2007). According to GN, "when arguments were presented [by SW during the SW application prosecution] to the Examiner that one component systems and two component systems were patentably distinct, the present two component SW claims were allowed over prior art which was directed to a single component system" (Paper 38, page 12, ¶ 29). Our principal difficulty with the prosecution history argument is that the argument does not take into account (1) the seemingly contrary position expressed by the examiner in the Rule 609(b) statement which (2) necessarily is based on (a) the presumed prior art as represented by SW's claimed subject matter and (b) other prior art cited in the Rule 609(b) statement.

In effect what GN has asked us to do is accept Dr. RS's conclusions, without a sufficient underlying factual basis. For reasons given above, we decline to give much, if any, weight to Dr. RS's opinions, even though there was no cross-examination and even though the preliminary motion is not opposed. Alternatively, GN asks us to scour the record to see if somehow the position urged by GN may be supported. We likewise decline to dig into the record to see if we might be able to somehow make

out a case for GN; we will not take on the role of an advocate for GN.

2.

While not necessarily applicable to the case before us, we take this opportunity to make the follow observations with the hope that they may be of help to parties involved in interferences, as well as patent practitioners who represent those parties.

The board's ex parte and interference backlogs are considerable. The board, as a whole, has had some success this past year in reducing both backlogs. However, as a matter of policy, we cannot, and should not, undertake in interference cases to fill gaps in proofs which are otherwise manifestly insufficient. In an interference, the burden is on a party--not the board--to establish its case. The Trial Section recently has experienced numerous--far too many--situations where a party in an interference, in essence, says:

Here is the evidence. I do not have time to discuss the evidence in detail, but if you look through it, you will see the merit of my case.

To the extent that there are parties, or patent practitioners representing those parties, who have a notion that we are going to do their job, now would be a good time for those parties and counsel to disabuse themselves of that notion. We simply are not

going to expend board resources to try to "bail out" those who ask us to search a record to prove (or disprove) their case.

DeSilva v. DiLeonardi, 181 F.3d 865, 866-67 (7th Cir 1999) ("A brief must make all arguments accessible to the judges, rather than ask them to play archaeologist with the record.").

The time it would take us to "bail out" those who file sloppy motions is much better spent on attending to cases, both ex parte and interferences, where parties and their attorneys have presented proper motions based on proper records. There is no substitute for a properly filed motion which is fully supported by citations to a properly filed record coupled with a concise argument in support of a position.

The Trial Section recently has had considerable experience with preliminary motions filed following a settlement. Understandably, such preliminary motions are often unopposed. The fact that a motion is not opposed does not operate to relieve a party from the burden of proof imposed on all parties filing motions by 37 CFR § 1.637(a).

We are under an impression--perhaps incorrectly--that parties filing an unopposed motion after "settlement" seem to believe that the board will, or should, "automatically" grant the motion. Many unopposed motions make only a minimal, often insufficient, effort to factually or legally support a position urged.

In a contested motion, the board can expect opposing parties to present both evidence and argument in favor of and against a particular position. Once there is a settlement, the interference at least in some respects ceases to be an adversarial proceeding. We encourage settlement and assume that all settlement efforts are good faith efforts. However, the fact that an interference may have been settled, pending resolution of certain patentability issues, should not be taken as a license to authorize a party to file a profunctorial motion that the party feels we will, or have to, "automatically" grant. Moreover, settlement does not invest a party with authority to engage in shenanigans in an attempt to bamboozle the board into a certain result. The public interest associated with the grant of a patent for a patentable invention and patent practitioner's ethical obligation for candor before this tribunal simply demand more.

