

The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper No. 119

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

GERVAIS DIONNE,

Junior Party,
(Patent 5,538,975),

v.

LIOTTA,

Senior Party
(Application []).

Patent Interference No. 104,333

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

Per curiam.

MEMORANDUM OPINION and ORDER
(Decision on Preliminary Motions)

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III. Opinion

A. Construction of the Count

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In interpreting the claims involved in the interference, we apply the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise may be afforded by written description contained in applicant's specification. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Giving the claims recited in the count the broadest reasonable meaning, we conclude that one of ordinary skill in the art would interpret the claims to encompass the (-) FTC enantiomer as well as substantially pure (-) FTC and their pharmaceutically acceptable salts thereof and pharmaceutical compounds comprising the (-) FTC enantiomer.

Additionally, we note that Liotta has directed our attention to a Final Decision issued in Interference 104,201, which is said to hold that a claim directed to the (-) enantiomer of a compound, without specifying a level of purity covers all mixtures that contain that compound including a racemic mixture of the (+) and (-) enantiomers. (Liotta Revised Preliminary Motion 1, Paper No. 52, p. 19). The fact that another motions panel in another interference faced with a different evidentiary record may have reached a different claim construction comes as no surprise and in any event is entitled to no precedential value. Construction of the meaning of words in a patent claim is an issue of law to be resolved based on the facts of each case. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 34 USPQ2d 1321, 1329-30 (Fed. Cir. 1995) (in banc), aff'd 517 U.S. 370, 391, 116 S.Ct. 1384, 1396 (1996) (interpretation of the word "inventory" [in a patent claim] in this case is an issue for the judge, not the jury * * *.); *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1577, 40 USPQ2d 1019, 1022 (Fed.

Cir. 1996) (significance to be given a limitation in a patent claim is a question of law which is resolved based on particular facts).

Liotta also directs our attention to *In re Williams*, 171 F.2d 319, 80 USPQ 150 (CCPA 1948) which is said to hold "that a claim to a laevo optical isomer without mention of a purity state read on a racemic mixture." (Liotta Reply 1, Paper No. 101, p. 1). *Williams*, however, involved a disputed claim directed to a laevo rotary form of a compound that was "substantially free from the dextro rotary form." *Williams* does not **require** a claim construction that a claim to a laevo optical isomer without mention of a purity state read on a racemic mixture. Moreover, the U.S. Court of Customs and Patent Appeals ("CCPA") issued words of caution in applying the *Williams* holding. Specifically, in the subsequent decision in *In re Adamson*, 47 CCPA 839, 275 F.2d 952, 125 USPQ 233 (1960), the CCPA indicated that the *Williams* decision resulted from the absence of relevant available evidence. In contrast to *Williams*, the evidence presented in this interference amply supports our claim construction.

B. Overview of Preliminary and Miscellaneous Motions

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1. Dionne Preliminary Motion 3

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a. The Person of Ordinary Skill in the Art

There exists a dispute as to knowledge and experience attributed to the "person of ordinary skill in the art." In particular, Dionne argues for a higher level of skill than that sought by Liotta. For example, Dionne's experts allege that:

The subject matter of the '160 Application relates, inter alia, to the *synthesis and resolution of FTC*. In my opinion, the person of ordinary skill in the art of the synthesis and resolution of organic compounds, such as FTC, at all times relevant to my analyses in this case would be someone with a *Ph.D. in organic chemistry* and a *minimum of two years further experience in the synthesis and resolution of organic, medicinal compounds*. This person would be experienced in the use of various resolution techniques, including chromatography (including high performance liquid chromatography or "HPLC") and/or enzymatic resolution techniques . . .

(Declaration of Dr. Barry Trost, ¶ 12, DX 2048; see also, Declaration of Dr. Iving W. Wainer, ¶ 4, DX 2155; Second Declaration of Dr. J. Bryan Jones, DX 2144, ¶ 5). In contrast, Liotta experts argue:

The art to which the '160 application relates is chemistry and, more particularly, *organic chemistry*. Based upon my years of experience and knowledge, I believe that one of ordinary skill in the art would have a *B.S. in chemistry* (or a related science) and *four or five years of chemical laboratory experience*. I do not believe, as Dionne's declarants suggest, that ordinary skill in the art would necessarily have been experienced in chiral HPLC and/or enzymes and would certainly not have been experienced in all resolution techniques.

(LAX 1004, Klibanov Opposition Decl., ¶ 10, emphasis added; see also, Pirkle Opposition Decl. LAX 1005, ¶ 10).

It is recognized that the person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986). In determining this skill level, the Board may consider various factors including "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *Id.* In a given case, every factor may not be present, and one or more factors may predominate. *Id.* at 962-63, 1 USPQ2d at 1201.

In support of their allegations, Liotta's experts note that in BioChem Pharma, the real party in interest in Dionne '975, hired a Ms. Marika DiMarco in 1988 to start up and run the company's chromatography lab. At that time, Ms. DiMarco had a B.S. in biology and seven years of industrial experience in chromatography. During the years of 1988 to 1990, Ms. DiMarco was asked by BioChem Pharma to do research on the resolution of a nucleoside that was related to FTC. (LAX 1004, ¶ 10; LAX 1005, ¶ 10). Additionally, Dr. Klibanov states that none of the inventors named in Dionne's or Liotta's applications had the qualifications espoused by Dionne. (LAX 1004, ¶ 11).

Beyond the conclusory statements of its experts, Dionne has failed to identify sufficient evidence in support of its alleged skill level. Indeed, Dionne's expert, Dr. Jones has indicated that techniques for separating the enantiomers in a racemic mixture like FTC have been taught in *undergraduate* as well as graduate level organic chemistry courses. (DX 2009, ¶ 16,19 and 25). Similarly, Dionne's expert, Dr. Wainer has stated that, while working with the FDA (pre-1990), his goal was to develop a chemical assay for separating the component enantiomers of racemic mixtures that could be used by an "average chemist" without any type of advanced training. (DX 2040, ¶17). Moreover, Dionne's expert, Dr. Trost states that his lab had obtained separations of various racemates using chiral HPLC columns with the work being "carried out on a routine basis by students with Bachelor's degrees in chemistry." (DX 2048, ¶21). Thus, while Liotta's supporting evidence on this issue is meager, Liotta's evidence combined with the aforementioned statements of Dionne's experts is arguable sufficient to support a finding that:

One of ordinary skill in the art would have a B.S. in chemistry (or a related science) and have four or five years of chemical laboratory experience. The

person of ordinary skill in the art would not necessarily have been experienced in resolution techniques.

(LAX 1004, ¶ 10; LAX 1005, ¶ 10).

While the foregoing finding may resolve a factual dispute among the parties, its overall relevance is not apparent. We have noted a tendency for parties involved in interferences to "define" the level of skill by reference to an academic degree (e.g., a B.S., and M.S. or a Ph.D.) and/or by reference to a person having a certain number of years of particularized experience (e.g., in a chemical laboratory). As we have noted on other another occasion,¹ the parties references to degrees and experience are not of much assistance to us as fact-finders. None of the members of this motions panel has a B.S. degree in chemistry. Even if one of us had such a degree, we would know only what we think a person with a B.S. in chemistry awarded in the year we graduated from our particular college might have known.

Likewise, we have no idea what an individual may have learned through four or five years of chemical laboratory experience. Abstract references to a period of experience are essentially meaningless. We suppose the precise knowledge acquired as a result of experience might well be a function of the type of laboratory and the type of work actually done in that laboratory. To the extent that any member of this panel may have chemical laboratory experience beyond college, none of it occurred at any time relevant to the issues in this interference.

More to the point is the proposition that our personal understanding of the knowledge of individuals with a B.S. in chemistry and any number of years of laboratory experience is essentially irrelevant. *Cf. Fromson v. Antieck Printing Plates, Inc.*, 132 F.3d 1437, 1448, 45

¹ *Argyropoulos v. Swarup*, 56 USPQ2d 1795, 1807 (Bd. Pat. App. & Int. 2000) (non-precedential).

USPQ2d 1269, 1277 (Fed. Cir. 1997) (Mayer, C.J., concurring) (I "know" what anodization means from my own undergraduate studies and experiments; the concept is not difficult and I need no further education to grasp it. I happen to have a dictionary in my chambers from the era pertinent here, which would confirm my "knowledge" about anodization. ***. But, I am neither an expert in the field nor one of ordinary skill in the art despite how much I think I "know" about a process I once studied. Nor do my colleagues on this court or on the district court possess such expertise, and even if they did, they would have to defer to the record made in the case.).

As Chief Judge Mayer notes, what counts is what is shown in a record. With respect to the skill of an ordinary artisan, we believe a party should be able to refer to standard texts and other publicly available documents to support what a hypothetical person of ordinary skill is presumed to know. Alternatively, it might be appropriate for a person with knowledge in a particular field to give testimony with respect to particular facts and techniques known by the average person working in that field, preferably citing documents in support thereof. Significantly, the testimony (but not our personal knowledge) may be cross-examined. A party in an interference cannot be expected to cogently brief an issue and argue its case if it also has to figure out what our personal knowledge might be.

In evaluating the enablement issues raised in this interference, we have given minimal, if any, weight to degrees and abstract descriptions of the length of service in chemical laboratories. Rather, consistent with our requirement that an expert witness state the underlying basis for opinion,² we have considered the testimony of the experts on the issue of ordinary skill in the art

² Notice Declaring Interference, ¶46.

in light of the technical documents and concrete experience to which those experts have made reference.

b. The '160 Application Lacks Enablement for the Resolution of FTC Enantiomers

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ii. Prior Art Fails to Enable Chiral HPLC Resolution of FTC

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We note that Biochem Pharma, Inc., the real party in interest in Dionne '975, is also involved in Interference No. 104,369 ("'369"). Specifically, the '369 interference involves Belleau (real party in interest, Biochem Pharma, Inc.) versus []. The panel that decided the preliminary motions in '369 interference is the same as in the present interference.

During the '369 interference, Belleau (Biochem Pharama) argued that as of January 3, 1991, one skilled in the art would have been able to obtain the (-)-enantiomer of [] in practically pure form without undue experimentation. In the '369 interference, this panel concluded that:

Based on the evidence that has been presented to us, we are not convinced that the amount of experimentation required to obtain (-)-enantiomer, according to either of the above two [claim] interpretations, would have been undue at the time the '039 application was filed.

(Interference 104,369, Paper No. 189, Decision on Preliminary Motions, pages 27-28, emphasis added).

The present interference involves at least one party that was not involved or otherwise related to the parties involved in the '369 interference. Furthermore, the findings and conclusions of the '369 decision were based upon a different evidentiary record.

To the extent the findings and conclusions of the '369 decision differ from those made in the present interference, we remind the parties that each interference is decided based on the specific facts and subject matter in dispute as well as the evidence that is presented during the interference. Moreover, as a matter of due process, each new party in an interference is entitled to make its own case. Cf., *Blonder-Tongue Laboratories, Inc. v. University of Ill. Foundation*, 402 U.S. 313, 169 USPQ 513 (1971).

* * * * *

12. Liotta "Preliminary" Motion 3

Liotta's "Preliminary" Motion 3, in actuality a miscellaneous motion, requests entry of an order pursuant to 37 CFR § 1.614(c) instructing the examiner of Liotta's '730 application to enter the Supplemental Amendment and Information Disclosure Statement ("IDS") filed by Liotta November 17, 1999. Moreover, Liotta requests that the examiner return a signed Form PTO 1449 to Liotta indicating that the references cited in the IDS were considered. (Liotta Preliminary Motion 3, Paper No. 118, p. 1). This motion is unopposed.

The consideration of an IDS by an examiner and its subsequent entry into Liotta's '730 application file is an *ex parte* matter. We see no compelling reason for this *inter parte* proceeding to be suspended or delayed while the examiner considers the IDS of November 17, 1999.³ After the termination of this interference, the application will be returned to the examiner for action not inconsistent with action taken by this Board. It is during this *ex parte* proceeding that Liotta's IDS should be reviewed and considered.

³Dionne has not filed, nor requested to file, a motion seeking the unpatentability of Liotta's claims under 37 CFR 1.633(a) based upon the art cited in the IDS.

Additionally, we note that Liotta's Supplemental Amendment requests that the specification be amended to reflect claims to certain earlier filed applications. As with the IDS, the entry of this amendment to the specification is best left for *ex parte* consideration after the termination of this interference.

For the reasons provided above, Liotta's "Preliminary" Motion 3 is *dismissed without prejudice* to the IDS and amendment being considered when *ex parte* proceedings resume.

* * * * *

FRED E. McKELVEY)	
Senior Administrative Patent Judge)	
)	BOARD OF PATENT
RICHARD TORCZON)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
SALLY GARDNER-LANE)	
Administrative Patent Judge)	