

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte THEOHARI C. THEOHARIDES

Appeal No. 2003-1418¹
Application No. 09/056,707

ON BRIEF

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

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 3, 4, and 6. Claims 7-21 are also pending but have been withdrawn from consideration. See Paper No. 11, mailed July 12, 2000.

The claims on appeal read as follows:

1. A method of treating an atopic allergic disease in a mammal characterized by numbers of mast cells or levels of biochemicals secreted by said mast cells sufficiently high to cause said atopic allergic disease, comprising the step of the administration to said mammal of a pharmaceutically effective amount of a proteoglycan

¹ Appellant filed a Petition to Make Special (see Paper No. 30, filed Dec. 19, 2002), which was granted (Paper No. 31, mailed Feb. 4, 2003). Accordingly, we have taken up the appeal in this case out of its usual turn. See MPEP § 708.02.

with mast cell secretion inhibitory activity, said proteoglycan comprising a chondroitin sulfate, alone or together with one or more synergistic adjuvants.

3. The method of claim 1, wherein said adjuvant is a flavonoid.
4. The method of claim 3, wherein said flavonoid is selected from the group consisting of myrisetin, quercetin, kaempferol, genistin, a 2-phenylchromone and 2-phenylbenzopyrone.
6. The method of claim 1, wherein said atopic allergic disease is selected from the group consisting of allergic asthma, allergic rhinitis, allergic conjunctivitis, allergic otitis media, allergic dermatitis, food allergy and allergic urticaria.

The examiner relies on the following references:

Wagner et al. (Wagner)	5,260,335	Nov. 9, 1993
Ahmed	5,980,865	Nov. 9, 1999

Claims 1, 3, 4, and 6 stand rejected under 35 U.S.C. § 103 as obvious in view of Ahmed and Wagner.

We reverse.

Background

“Mast cells are a normal component of connective and mucosal tissues and play an important role in allergy and inflammation.” Specification, page 1. “Each mast cell contains up to 500 secretory granules, each storing more than 20 potent biological compounds. Mast cells secrete the contents of these granules (i.e., degranulate) when triggered by various specific and non-specific mechanisms, such as the allergic reaction involving immunoglobulin E (IgE) and antigen.” Id.

The specification discloses “a method for preventing and treating the harmful biological effects of secretion of biochemicals from mast cells in the organs of warm blooded animals and more especially human beings. These harmful effects include allergy (including but not limited to allergic conjunctivitis, allergic rhinitis, allergic otitis, asthma, and atopic dermatitis).” Id., page 4. “[T]he method consists of administering to said animals and especially to human beings an amount of a proteoglycan with mast cell secretion inhibitory activity, such as chondroitin sulfate.” Id., pages 4-5. The proteoglycan can also be administered in combination with “one or more synergistic adjuvants (such as those belonging to the class of flavonoids . . .).” Id., page 5.

“Proteoglycans are high molecular weight polyanionic macromolecules (heteropolysaccharide) consisting of many different glycosaminoglycan chains linked covalently to a protein core that constitutes up to about 5% of the total macromolecules. . . . Chondroitin sulfate, like other proteoglycans, is naturally occurring, and is a natural constituent of connective tissues. It is available over the counter as a food supplement.” Id., page 4.

Discussion

The claims are directed to a method of treating an atopic allergic disease, such as allergic asthma or allergic rhinitis, by administering a pharmaceutically acceptable amount of chondroitin sulfate, either alone or in combination with a synergistic adjuvant.

The examiner rejected the claims as obvious over Ahmed and Wagner. The examiner cited Ahmed as “teach[ing] proteoglycans such as chondroitin sulfate to be useful in treating allergic conditions such as asthma [and] allergic rhinitis.” See Paper No. 11, mailed July 12, 2000, page 3. The examiner cited Wagner as teaching “the flavonoid quercetin to be useful in treating allergic diseases and bronchial asthma.” Id. Thus, she concluded that it would have been obvious to treat asthma with a combination of chondroitin sulfate and quercetin, since treatment of asthma with each ingredient individually was taught in the prior art. See id., pages 3-4.

We begin by construing the claims. “[N]ot unlike a determination of infringement, a determination of anticipation, as well as obviousness, involves two steps. First is construing the claim, . . . followed by, in the case of anticipation or obviousness, a comparison of the construed claim to the prior art.” Key Pharms. Inc. v. Hercon Labs. Corp., 161 F.3d 709, 714, 48 USPQ2d 1911, 1915 (Fed. Cir. 1998).

Claim 1 is directed to a method of treating an atopic allergic disease by administering “a pharmaceutically effective amount of a proteoglycan with mast cell secretion inhibitory activity, said proteoglycan comprising a chondroitin sulfate.” The specification states that chondroitin sulfate is a proteoglycan, and that proteoglycans, in turn, are “high molecular weight polyanionic macromolecules (heteropolysaccharide) consisting of many different glycosaminoglycan chains linked covalently to a protein core.” Page 4. Thus, when the claims are read in light of the specification, they should be construed as

being directed to a method of treating atopic allergic disease by administering the proteoglycan chondroitin sulfate, i.e., the intact, high molecular weight macromolecule consisting of many different glycosaminoglycan chains linked covalently to a protein core.

Ahmed teaches a method of treating late phase allergic reactions, such as asthma or allergic rhinitis, by administering “ultra-low molecular weight heparins (ULMWH) or other sulfated polysaccharides having average molecular weights of about 1,000-3,000 daltons.” Abstract. With regard to chondroitin sulfate, Ahmed states that

[w]hile the sulfated polysaccharides used in the method and compositions of the invention are generally referred to herein as ultra-low molecular weight heparins, i.e., ultra-low molecular weight fractions derived from naturally occurring heparin . . . , the invention may also encompass the use of sulfated polysaccharides derived from . . . chondroitin sulfate. . . . The subject sulfated polysaccharide fractions must, however, have an average molecular weight of about 1,000-3,000 daltons.

Column 10, lines 38-48.

We agree with Appellant that this disclosure would not have suggested the instantly claimed method. The following passage from Appellant’s brief sums up the argument well:

The sole reference to proteoglycans other than heparin is found in col. 10, lines 38-52, in a single sentence in which chondroitin sulfate among other proteoglycans is mentioned. However, in this same location is found the statement that the drugs described are derived from heparin or other proteoglycans, that is to say, they are low molecular weight sulfated polysaccharides (1,000-3,000 Da) that have been chemically removed from heparin or other proteoglycans, and isolated. Such sulfated polysaccharides, by definition, contain no protein and thus are no longer proteoglycans; they are different chemical entities. Thus, this reference neither suggests nor

provides motivation for using intact chondroitin sulfate to treat subjects.

Appeal Brief, page 10 (emphasis in original). That is, although Ahmed suggests treatment of asthma and allergic rhinitis with sulfated polysaccharides derived from chondroitin sulfate and having a molecular weight of 1000 to 3000 daltons, it does not suggest modifying the disclosed method of treatment by administering intact chondroitin sulfate, as required by the instant claims. Wagner does not remedy this deficiency and therefore the cited references do not support a prima facie case of obviousness.

Summary

The references relied on by the examiner would not have suggested the instantly claimed method to a person of ordinary skill in the art. The rejection under 35 U.S.C. § 103 is reversed.

REVERSED

Sherman D. Winters)
Administrative Patent Judge)
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) BOARD OF PATENT
William F. Smith)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
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Eric Grimes)
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