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Paper No. 9
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME CORP.,
Petitioner,

v.

WYETH LLC,
Patent Owner.

Case PGR2017-00016 (Patent 9,399,060)
Case PGR2017-00017 (Patent 9,399,060)[1]

Before TONI R. SCHEINER, GRACE KARAFFA OBERMANN, and ULRIKE W. JENKS, *Administrative Patent Judges.*

OBERMANN, *Administrative Patent Judge.*

DECISION
Denying Institution of Post Grant Review
35 U.S.C. § 324; 37 C.F.R. § 42.208

[1] This decision addresses issues common to both proceedings; therefore, we issue a single decision to be entered in each case. We refer to PGR2017-00016 as "PGR016" and PGR2017-00017 as "PGR017." For convenience, unless otherwise noted, citations are to papers and exhibits filed in PGR016.

I. INTRODUCTION

Petitioner filed a Petition for post grant review of claims 1–13 of U.S. Patent No. 9,399,060 (Ex. 1001, "the '060 patent"). Paper 1 ("Pet."). Patent Owner filed a timely Preliminary Response. Paper 8 ("Prelim. Resp."). Based on the information presented in the Petition and the Preliminary Response, we hold that Petitioner has not demonstrated adequately that the '060 patent is eligible for post grant review.

Accordingly, we deny the Petition.

Related Proceedings

Petitioner identifies as related matters three Petitions for *inter partes* review of U.S. Patent No. 8,562,999 ("the '999 patent"). Pet. 9 (citing Cases IPR2017-00378, IPR2017-00380, and IPR2017-00390). The claims in the '999 patent are directed to formulations containing polysaccharide-protein conjugates. The Board instituted trial in those three proceedings on June 13, 2017.

Petitioner states that it "is unaware of any other judicial or administrative matter that would affect, or be affected by, a decision in this proceeding." Pet. 9. However, Petitioner filed three requests for *inter partes* review of the '060 patent a few days after filing the instant Petition. *See* Cases IPR2017-01211, IPR2017-01215, and IPR2017-01223. Concurrently herewith, we issue decisions in those three related proceedings.

The '060 Patent (Ex. 1001)

The '060 patent issued from Application No. 14/322,057 ("the '057 application"), filed on July 2, 2014. The '057 application is a continuation of Application No. 13/439,111, filed April 4, 2012, now U.S. Patent No. 8,808,708; which is a continuation of Application No. 12/357,853, filed

January 22, 2009, now U.S. Patent No. 8,895,024; which is a continuation of Application No. 11/395,593, filed March 31, 2006, now abandoned; which claims the benefit of the filing date of U.S. Provisional Patent Application No. 60/669,605, filed April 8, 2005. We collectively refer to the non-provisional applications, filed prior to the '057 application, as "the non-provisional '060 parent applications." That history is important because this case turns on whether Petitioner shows sufficiently that at least one claim has an effective filing date after March 16, 2013—a showing necessary to demonstrate that the '060 patent is eligible for post grant review. Pet. 49–63.

The '060 patent, entitled "Multivalent Pneumococcal Polysaccharide-Protein Conjugate Composition," relates to an immunogenic composition comprising polysaccharide-protein conjugates containing capsular polysaccharides prepared from different *Streptococcus pneumoniae* serotypes. Ex. 1001, Abstract. The different serotypes represented in the immunogenic composition include serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19 A, 19F, and 23 F. *Id*. We adopt the parties' convention and refer to the 13-valent pneumococcal conjugate as the "13vPnC" vaccine. *See, e.g.*, Pet. 1; Prelim. Resp. 32.

The polysaccharides were obtained from *S. pneumoniae* cell cultures that were harvested and then lysed to release cell-associated polysaccharides into the culture medium. *Id*. at 11:25–12:10. The polysaccharide containing lysate was clarified by continuous flow centrifugation followed by microfiltration. *Id*. at 12:25–27. The purification of the pneumococcal polysaccharide consisted of several steps including: concentration/diafiltration operations, precipitation/elution, column chromatography, and depth filtration. *Id*. at 12:30–34. These steps were repeated for each individual serotype.

The ’060 patent explains that the purified polysaccharides are chemically activated with sodium periodate so that they are able to chemically interact with the carrier protein in order to form a glycoconjugate. *Id*. at 8:1–3. The ’060 patent explains that “different serotype saccharides follow different pathways for activation (hydrolysis or no hydrolysis prior to [sodium periodate] activation) and conjugation (aqueous or DMSO[2] reactions).” *Id*. at 24:9–12. For example, the ’060 patent explains that for the serotype 1 polysaccharide the chemical activation involves treating the purified polysaccharide with sodium carbonate to achieve partial deacetylation, followed by neutralization, and finally oxidation in the presence of sodium periodate. *Id*. at 13:50–56. For the serotype 3 polysaccharide the chemical activation process involves treating the purified polysaccharide with acetic acid to hydrolyze the polysaccharide, followed by adding sufficient magnesium chloride to achieve a final concentration of 0.1M, before proceeding to the oxidation step in the presence of sodium periodate. *Id*. at 16:39–47. The serotype 19A polysaccharide activation process involves adding sodium acetate before reaching the oxidation step with sodium periodate. *Id*. at 21:19–22.

The ’060 patent explains that the conjugation step involves lyophilizing the activated polysaccharide and then mixing in the lyophilized carrier CRM_{197} protein[3] and reconstituting the dried components before adding the crosslinking agent. *Id*. at 14:7–12. The lyophilized polysaccharide and

[2] “DMSO” is dimethylsulfoxide. Ex. 1001, 19:14.
[3] CRM_{197} (Wyeth, Sanford, N.C.) is a non-toxic variant (i.e., toxoid) of diphtheria toxin isolated from cultures of *Corynebacterium diphtheria* strain C7 (β197) grown in casamino acids and yeast extract-based medium. Ex. 1001, 8:19–22.

lyophilized CRM_{197} protein are reconstituted in either DMSO or in an aqueous buffer before proceeding to the conjugation reaction with sodium cyanoborohydride to obtain the polysaccharide-protein conjugate. *Id*. at 25:1–50, 26:28–52; *see* 16:58–67 (Example 4: Preparation of Serotype 3 Pneumococcal Saccharide CRM_{197} Conjugate).

The ’060 patent specification explains that the final immunogenic composition was formulated by combining the individual polysaccharide-CRM_{197} protein conjugates. The formulation contains 2–2.2 µg of each saccharide, except for 6B at 4–4.4 µg, approximately 29 µg CRM_{197} carrier protein; 0.125 mg of elemental aluminum (0.5 mg aluminum phosphate) adjuvant, as well as sodium chloride and sodium succinate buffer as excipient. *Id*. at 3:9–15, 29:60–30:41.

Illustrative Claims

Claims 1 and 2, reproduced below, illustrate the subject matter:

> 1. A multivalent immunogenic composition comprising polysaccharide-protein conjugates and a physiologically acceptable vehicle, wherein each of the conjugates comprises a capsular polysaccharide from a different serotype of *Streptococcus pneumoniae* conjugated to a carrier protein, wherein the serotypes comprise 4, 6B, 9V, 14, 18C, 19F, 23F and at least one additional serotype, wherein the additional serotype is serotype 3, and wherein the carrier protein is CRM_{197}.
>
> 2. The immunogenic composition of claim 1, wherein the additional serotypes consist of serotypes 1, 3, 5, 6A, 7F and 19A.

Ex. 1001, 35:16–26.

Evidence Relied Upon

Petitioner raises ten distinct grounds of unpatentability; six in PGR016 (Pet. 10–11) and four in PGR017 (PGR017, Paper 1, 9). Our decision to deny

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