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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/568,266	10/20/2017	Hyeon-A YIM	068374-000052	1285
20230 7590	02/26/2019		EXAMINER	
Vorys, Sater, Seymour and Pease LLP 1909 K St., NW 9th Floor WASHINGTON, DC 20006-1152			SONG, JIANFENG	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Claims 1-15 are pending and under examination.

Priority

Acknowledge is made that this application is national stage of international application PCT/KR2016/004084, filed on 04/20/2016; which claims priority from Korean patent application KR1020150056977, filed on 04/23/2015.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/20/2017 is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*.

While all of the factors have been considered, only those required for a *prima facie* case are set forth below.

The specification discloses a process for preparing a polyurethane foam dressing in which an anti-inflammatory agent is homogeneously dispersed, the process comprising: (a) mixing **dexibuprofen**; one or more dispersing agents selected from the group consisting of methanol, ethanol, n-propanol, isopropanol, ethyl acetate and n-hexane; and a polyurethane prepolymer comprising a polyol and an isocyanate to obtain a drug-containing polyurethane prepolymer.

The claims are drawn to a process for preparing a polyurethane foam dressing in which an anti-inflammatory agent is homogeneously dispersed, the process comprising: (a) mixing an alkaline anti-inflammatory agent having a pKa value more than pKa 7 (**interpreted as sodium dexibuprofen**); one or more dispersing agents selected from

the group consisting of methanol, ethanol, n-propanol, isopropanol, ethyl acetate and n-hexane; and a polyurethane prepolymer comprising a polyol and an isocyanate to obtain a drug-containing polyurethane prepolymer.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claim indicates that these claims are drawn to a process for preparing a polyurethane foam dressing in which an anti-inflammatory agent is homogeneously dispersed, the process comprising: (a) mixing an alkaline anti-inflammatory agent having a pKa value more than pKa 7 (**interpreted as sodium dexibuprofen**); one or more dispersing agents selected from the group consisting of methanol, ethanol, n-propanol, isopropanol, ethyl acetate and n-hexane; and a polyurethane prepolymer comprising a polyol and an isocyanate to obtain a drug-containing polyurethane prepolymer.

There is substantial difference regarding solubility and reactivity between anti-inflammatory agent **dexibuprofen** and the corresponding sodium **dexibuprofen** in the polymerization process. The disclosure of a process for preparing a polyurethane foam dressing from anti-inflammatory agent **dexibuprofen** does not provide an adequate description of the claimed invention of a process for preparing a polyurethane foam dressing from sodium **dexibuprofen**.

Weighing all the factors, the breadth of the claims reading on alkaline anti-inflammatory agent yet to be discovered, the difference in solubility and reactivity in the

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