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5514	7590	02/28/2014	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 1290 Avenue of the Americas NEW YORK, NY 10104-3800			BARHAM, BETHANY P	
			ART UNIT	PAPER NUMBER
			1615	
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			02/28/2014	PAPER

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.

DETAILED ACTION

Summary

The present application is being examined under the pre-AIA first to invent provisions. Receipt of the multiple IDSs filed is acknowledged. Receipt of the Claim Amendments and Response filed on 01/27/14 is also acknowledged. Claims 1, 3, 5-13 and 16-18 are pending.

Election/Restrictions

Applicant's election with traverse of Group in the reply filed on 01/27/14 is acknowledged. The traversal is on the ground(s) that a single special technical feature now claimed is not taught by US 2006/0160841. This is not found persuasive because the claims as originally presented lack a special technical feature and Groups I-VI differ in scope and have different modes of operation, effects, and functions. Specifically, as pointed out in the 10/29/13 Election/Restriction requirement, Group I and Group II have different sizes and as such the common technical feature is "[a] composition comprising crystalline apixaban particles and a pharmaceutically acceptable diluent or carrier" and secondly this common technical feature is known in the art as evidenced by at least US 2006/0160841 which teaches a slurry of PG and water comprising N-1 form of apixaban particles of D90 of less than 20 microns (see Examples). As such, claims 13 and 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim.

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Claims 1, 3, and 5-12 will be examined in the instant application. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/27/14. The requirement is still deemed proper and is therefore made FINAL.

Priority- Claim Rejections - 35 USC § 112

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of 35 U.S.C. 112(a) or the first paragraph of pre-AIA 35 U.S.C. 112, except for the best mode requirement. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 61/308056, fails to provide adequate support or enablement in the manner provided by 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph for one or more claims of this application. There is no support for "D₉₀ equal to or less than about 89 μm" of claim 1 from which all other claims depends.

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As such the priority of claim 1 and dependent claims thereon is the filing date of the instant application.

NEW-Claim Rejections - 35 USC § 112

The following is a quotation 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 35 U.S.C. 112 (pre-AIA), first paragraph:

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 9-10 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 instant claims claim functional language without any actual structure. The claims claim AUC and/or Cmax that is at least 80% of the mean AUC and/or Cmax observed for an equivalent formulation differing only in that the D₉₀ is 89microns which has to do with the specific structural components in the composition i.e. excipients like specific granulating agents such as microcrystalline cellulose, lubricants, etc. such as those in instant Tables 3-5, but such functional limitations of

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