

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and AMNEAL
PHARMACEUTICALS OF NEW YORK, LLC

Petitioners

v.

ALMIRALL, LLC

Patent Owner

Case: IPR2019-00207

U.S. Patent No. 9,517,219

**PETITIONERS' REPLY TO PATENT OWNER'S
PRELIMINARY RESPONSE**

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Petitioners' Reply to Patent Owner's Preliminary Response

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STATUTES

35 U.S.C. § 1211

35 U.S.C. § 314(a)1

35 U.S.C. § 325(d)1

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Amneal's Petition demonstrated that *inter partes* review ("IPR") should be instituted for all claims of U.S. Patent No. 9,517,219 ("the '219 patent").

Tellingly, Patent Owner Almirall, LLC ("Almirall") did not dispute the substantive merits of Amneal's grounds. Instead, Almirall limits its Preliminary Response ("POPR," Paper 8) to misleading and unavailing § 314(a) and § 325(d) arguments, both of which the Board should soundly reject.

First, Almirall seeks institution denial under 35 U.S.C. § 314(a) and the *General Plastic* factors in view of co-pending IPR2018-00608, which has been instituted, challenging U.S. Patent No. 9,161,926 ("the '926 patent"). The '219 patent is a *divisional* of the '926 patent. Almirall has failed to establish the *General Plastic* factors, and its arguments misstate facts and misapply the law. For example, this Petition is the first filed against the '219 patent, so it is *not* a follow-on of the sort governed by the *General Plastic* factors. Almirall tries to create the illusion that the '219 and '926 patents are the same, but cannot dispute that the '219 patent is a divisional patent, which means it is "independent and distinct" from the '926 patent. *See* 35 U.S.C. § 121.

Second, Almirall seeks denial of institution under 35 U.S.C. § 325(d). Remarkably, Almirall's argument essentially is that if an examiner applies a reference for a limitation during prosecution, then *any* other reference for that limitation would be *per se* cumulative. Almirall's untenable reading of § 325(d)

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