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Via ECF and Hand Delivery

Honorable Thomas P. Griesa
United States District Court
500 Pearl Street
New York, NY 10007-1312

Re: *Endo Pharmaceuticals Inc., et al. v. Actavis Inc., et al.*
Civil Action Nos 12-8985 and 13-0436 (TPG)

Endo Pharmaceuticals Inc., et al. v. Teva Pharmaceuticals USA, Inc. et al.
Civil Action No. 12-8060 (TPG)

Endo Pharmaceuticals Inc. v. Roxane Laboratories, Inc.
Civil Action No. 13-3288 (TPG)

Endo Pharmaceuticals Inc. v. Sun Pharmaceutical Industries, Ltd., et al.
Civil Action No. 13-4343 and 13-8597 (TPG)

Dear Judge Griesa:

We represent the Actavis defendants and write on behalf of Actavis and the other the defendants in the above-referenced cases to briefly respond to plaintiff Endo's letter of July 22 concerning the recent decision by the U.S. Patent and Trademark Office ("PTO") in an *inter partes* review proceeding between Endo and Amneal Pharmaceuticals concerning U.S. Patent 8,329,216 ("the '216 patent").

The PTO's decision has no bearing on the issues of validity of the '216 patent that were tried to this Court and currently pending decision, for at least the following reasons.

First, the *inter partes* review was initiated by Amneal Pharmaceuticals, and only Amneal and Endo were parties. None of the other defendants were parties to that proceeding. Rather, these defendants elected to have the issue of validity determined by this Court, which is their right under the Patent Act. The actions of others in an administrative proceeding before the PTO

in which these defendants were not parties does not and cannot bind these defendants or abridge their right to have the Court adjudicate the invalidity defenses on the record made at trial.

Second, a PTO *inter partes* review is completely different from a district court trial. The only evidence submitted to the PTO in an *inter partes* review comes in on the papers. There are no live witnesses. The only hearing in an *inter partes* review is a short oral argument of counsel, which in the case of two parties is generally limited to one hour. Unlike this Court, which had the benefit of a five-week trial with live witnesses, the PTO's decision was based solely on the papers and brief oral argument of counsel.

Third, given that Amneal was the only defendant involved in the *inter partes* review, the PTO did not hear from *any* of the other defendants' experts who testified at trial on the issue of obviousness, including Drs. Banakar, Kibbe, Mayersohn, and Deer. During the *inter partes* review, Amneal's obviousness arguments relied on declarations of Anthony Palmieri, Vivian Gray, and Mario Gonzalez. *See Final Written Decision*, IPR2014-00360 at 9, 17 (July 22, 2015). Amneal's expert Dr. Palmieri was the only defense witness at trial who also submitted a declaration to the PTO, but the subjects of his testimony and declaration were different. Specifically, Dr. Palmieri's declaration to the PTO concerned obviousness, but at the trial before Your Honor he testified only concerning anticipation (the on-sale bar defense). *See* Trial Tr. 2254:11–2350:4. In summary, there was no overlap between (i) the defense witnesses at trial who testified regarding obviousness and (ii) the witnesses who submitted declarations on behalf of Amneal to the PTO.

Fourth, the only challenge raised by Amneal before the PTO was obviousness over the prior art, pursuant to 35 U.S.C. § 103. The issues before the PTO did not include invalidity for lack of written description, 35 U.S.C. § 112(a), which these defendants presented at trial before Your Honor. As the Court will recall, the written-description defense arose from the lack of support for the broad dissolution ranges claimed by the '216 and '122 patents.[1] Similarly, the invalidity defense of the on-sale bar, under 35 U.S.C. § 102(b), was tried to this Court but not at issue before the PTO.

Further, Amneal's case before the PTO was limited to only two specific combinations of prior-art references: (1) obviousness over Maloney, and (2) obviousness over Oshlack and the Handbook of Dissolution Testing. In contrast, at trial before Your Honor, defendants presented additional and different combinations of prior art and evidence in their obviousness case (*see, e.g.,* DX-8001 (Dr. Banakar's demonstrative slides on the "Obviousness of the '122 and '216 Patents"), and presented testimony from experts that the PTO did not have the benefit of hearing.

[1] For reference, an example of the lack of connection was brought out on the cross-examination of named inventor Dr. Lee, who testified that he did not know if tablets at the high and low ends of the claimed ranges would actually work to provide pain relief, and conceded that the claimed ranges were essentially just made up arbitrarily. Trial Tr. 305:6–307:14.

For example, there was significantly less evidence before the PTO on the issue of the inherency of multiple peaks observed with oxymorphone, such that the PTO concluded that Amneal had not presented sufficient evidence to prove obviousness over Maloney. But at trial before this Court, inventor Dr. Lee admitted that the peaks claimed in the patents were an inherent property of oxymorphone. *See* Trial Tr. 297–303. Additionally, internal Endo documents and additional prior art not before the PTO, but brought out at trial, further demonstrated that the claimed multiple peaks were an inherent characteristic.[2]

Finally, the arguments Amneal presented to the PTO on obviousness over Oshlack and the Handbook of Dissolution Testing were focused on whether the basket and paddle methods for assessing in-vitro release of an opioid were equivalent. However, as the undersigned explained to the Court at closing, this was a crabbed and narrow approach because the issue is not simply if baskets and paddles give the exact same results. Rather, the issue is more broadly and properly understood as whether obvious formulations of extended release oxymorphone would fall within the broad dissolution ranges claimed by Endo.[3] And again, the evidence at trial before Your Honor was more complete than that presented to the PTO. For example, Endo's expert Dr. Fassihi conceded that Endo represented to the FDA that different dissolution methods (including different speeds and different apparatus) did not have an effect on the results of testing of Endo's crush-resistant extended release oxymorphone tablets. *See, e.g.,* Trial Tr. 2945:25-2948:11 (Fassihi – Cross) and DTX-2070 at 919, 931, 988.

For at least the reasons stated above, this Court should base its decision on the evidence that it heard at trial. *See Gator Tail, LLC v. Mud Buddy LLC,* ___ Fed. Appx. ___, 2015 WL 3833465, at *4 (Fed. Cir. Jun. 22, 2015) (affirming district court's judgment of invalidity based on the trial record, which it considered "to be a more complete picture of the evidence," notwithstanding PTO's decision on reexamination that the claims were valid).

Respectfully submitted,

/s Charles A. Weiss

Charles A. Weiss

cc: All Counsel of Record (by ECF)

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[2] For example, inventor Troy McCall acknowledged that multiple peaks were observed in immediate release and controlled release oxymorphone consistent with other opioids. DTX-0976 at ENDO_OP_0213736. Endo also represented to the FDA that morphine and other opioids exhibit multiple peaks, and multiple peaks present in oxymorphone suggested a similarity to morphine and other opioids. DTX-1444 at ENDO_OP_0884173.

[3] *See, e.g.*, Trial Tr. 3111:24-3115:1 (Summation —Weiss).