IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., *et al.* Plaintiffs, v. SANDOZ INC., *et. al.* Defendants.	**1:20CV1589** **MEMORANDUM AND ORDER**

This matter is before the Court for final decision on patent-infringement charges arising under the Hatch-Waxman Act. D.I. 531, 532, 533, 534.

On the heels of a previous suit involving different patents but the same Abbreviated New Drug Applications, plaintiffs, Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc., have sued to enjoin defendants, Lupin Ltd. and Lupin Pharmaceuticals, Inc., Sandoz Inc. and Lek Pharmaceuticals d.d., and Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (among a number of now-settled defendants), from marketing generic versions of Myrbetriq, Astellas's extended-release formulation of the active drug mirabegron for the treatment of overactive bladder. Solving what is referred to as the "food effect"—that is, the drug's dangerous potency on an empty stomach contrasted by its inefficacy on a full one—U.S. Patent No. 10,842,780 claims the extended-release formulation of mirabegron comprising (as set out in Claim 1) a hydrogel-forming polymer, hydrophilic additive, and a dissolution limitation: that the dosage has dissolved no more than 39% at 1.5 hours and at least 75% after 7 hours. Following discovery and settlement by many defendants, the active parties convened for a five-day bench trial in February 2023.

On infringement, defendants contested only their proposed generics' satisfaction of the dissolution limitation (for reasons not relevant here) and, on invalidity, challenged the '780 patent for (primarily) failing the enablement requirement of 35 U.S.C. § 112. In brief, defendants argued that the '780 patent specification offers insufficient clarity to enable one skilled in the art to make the invention without undue experimentation. Astellas disagreed, arguing that the admittedly brief specification directs routine activity by highly-skilled artisans in a predictable art.

For present purposes, the Court assumes Astellas's version of the facts and accepts its argument, which it distilled in the following statement:

> The inventive concept of the '780 Patent was *discovering* the dissolution rate that would address the food effect and achieving it using *previously known* formulation technology.

D.I. 541 at 5 (emphasis added throughout). As the Court gathers, Astellas concedes that the '780 patent is enabled because it claims invalid subject matter: a natural law applied via routine, conventional, and well-known methods. *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66 (2012).

Claim 1 illustrates. The extended-release dissolution limitation (Mirabegron itself having been long known, *e.g.*, U.S. Pat. No. 6,346,532; *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, No. 16-cv-905, D.I. 1, ¶ 23), as Astellas admits, reflects merely the discovery of the food-effect-resolving dissolution profile. Such relation, which "exists in principle apart from any human action," sets forth a natural law. *Mayo*, 566 U.S. at 77.

And Astellas's Dr. Steven Little confirmed that the polymer and additive limitations amounted to no more than the directive, "apply it:"

> Q. Were sustained release hydrogel formulations *well-known* as of September 2008?

> A. Yes, they were.
>
> Q. And were sustained release hydrogels *well characterized* as of September 2008?
>
> A. Yes, in fact, I think I would go so far to say *they were probably the most well characterized extended[-]release oral dosage form* for all of the different ones. There were more products approved, to my recollection, than any other of that type, they were the most well characterized.
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> Q. In September 2008, were sustained release hydrogels difficult to formulate?
>
> A. Well, from a pharmaceutical formulator's standpoint, no.
>
> Q. Were, as of September 2008, were sustained release hydrogels difficult to tune to achieve a specific dissolution profile?
>
> A. No, they weren't. *It's not just that the mechanisms are well understood and taught to somebody even before they got out of college*, but that you would have experience doing it yourself just because of the number of products on the market. And just given the amount of time, there is a large, large body of literature that shows over and over again the same kind of things that you see stated in the patent specification.

D.I. 530 at 60–61(Tr. 5-1243:15–44:15); *Mayo*, 566 U.S. at 79–80.

The asserted claims only simplify matters. Between narrowing the list of hydrogel-forming polymers to employ, excluding salt forms of mirabegron, formulating the dosage into a tablet, and claiming a method which employs the overactive-bladder remedy to treat, unsurprisingly, overactive bladder, asserted claims 5, 20, and 25 merely ease the skilled artisan's already routine task and tell doctors to administer the drug according to its intended use. *Mayo*, 566 U.S. at 78–79.

Further briefing on this matter would bring unnecessary delay and undue prejudice. To be clear, no substantive question remains—the Court directed the parties to brief the asserted claims' validity, D.I. 530 at 184 (Tr. 5-1367:12–17); this Court sits not an arbiter

to resolve disputes on the parties' favored terrain but as a United States District Court charged to apply the law given by Congress as interpreted by the Supreme Court and the Courts of Appeals for the Third and Federal Circuits; *Mayo* is settled, hornbook law with which learned patent-counsel is presumed familiar; and Astellas's precise and continued invocation of its facts and language (well beyond that cited here) sets the matter to rest. The question is instead whether further briefing might somehow absolve Astellas and permit it to recant its fundamental validity position. The Court, in its discretion, finds reopening of expert discovery, retrial, and redrafting of extensive post-trial briefing to be an unnecessary delay and unduly prejudicial to defendants.

In sum, Astellas's zealous defense has conceded more fundamental ground. Embodying no more than the discovery of a natural law applied via "well known techniques for formulating sustained release tablets," D.I. 541 at 1, the '780 patent claims ineligible subject matter.

THEREFORE, IT IS ORDERED THAT claims 5, 20, and 25 of U.S. Patent No. 10,842,780 are invalid. All pending motions are denied as moot.

Dated this 9th day of June, 2023.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge