IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ANACOR PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 18-202-IMK
MYLAN PHARMACEUTICALS INC., and MYLAN INC.,	)	
Defendants.	)	

REPLY IN SUPPORT OF ANACOR'S MOTION TO STAY CASE

The parties agree that a stay is appropriate while the PTAB addresses Mylan's challenge to the validity of the patents-in-suit. The parties also agree that a stay should terminate if the PTAB concludes that any claims are patentable. The parties' principal disagreement is whether, in the event that the PTAB determines that *all* of the claims of *all* of the patents-in-suit are unpatentable, the proposed stay should continue until after any appeal of that decision has run its course. Mylan's position—that a stay should terminate before completion of such an appeal—is wrong for two reasons.

First, Mylan would not be prejudiced by a stay through appeal. Anacor vigorously disputes that the patents-in-suit are invalid. But even assuming for the sake of argument that they are, Mylan has only two ways to trigger an early termination of the FDA's 30-month stay of approval: (1) prevail before the PTAB *and* on any appeal of the PTAB's decision; or (2) litigate this case to judgment and persuade this Court that the patents-in-suit are invalid on the basis of "clear and convincing evidence," a higher evidentiary burden than the one it must meet before the PTAB. The PTAB is expected to issue its final written decision in a few months, and there is no reason to believe that litigating this case all the way to judgment (under a different standard of

proof, and undoubtedly with different evidence than was presented to the PTO) would be any faster than completing an appeal of the PTAB's decision. If Mylan or the other challenger in the PTAB proceedings were to win the hypothetical appeal, the 30-month stay would end; if the hypothetical appeal was lost, then Mylan would be largely estopped from relitigating obviousness in this forum. Either way, the appeal would either resolve this matter completely or significantly impact its scope. Simultaneously litigating this case to judgment while a dispositive appeal of the PTAB's decision runs its course would waste the resources of the parties and the Court for no apparent reason.

In an effort to sidestep that conclusion, Mylan engages in speculative hand-waving by suggesting that it might raise defenses in this Court that are not available before the PTAB, "including, *inter alia*, non-infringement and non-prior art based invalidity." D.I. 39 at 4. In its September 17, 2018 notice letter to Anacor, Mylan had a statutory obligation to provide "a detailed statement of the factual and legal basis of [its] opinion that the [patents-in-suit are] invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II). The only factual and legal bases Mylan identified in that letter were obviousness and issue preclusion on the basis of a previous finding of obviousness involving a different patent.[1] The patents-in-suit issued over 18 months before Mylan sent its notice letter. Mylan has had ample opportunity to assess whether it has any defenses of non-infringement or non-prior art based invalidity, and it has not identified any. Mylan's speculation that it might yet conjure up such a defense is not a justification to waste resources in parallel litigation in this Court.

[1] Anacor did not include Mylan's notice letter as an exhibit to this reply because Mylan marked it "CONFIDENTIAL."

Second, Mylan turns the Hatch-Waxman Act on its head when it accuses Anacor of improperly seeking to "postpon[e] generic competition for Anacor's brand product" and obtain "an artificial extension of Anacor's monopoly," merely by asserting its patent rights. D.I. 39 at 1, 5. In the Hatch-Waxman Act, Congress struck a balance between innovator pharmaceutical companies such as Anacor and generic copyists like Mylan by including provisions to encourage the prompt and fair resolution of patent disputes. Because Anacor sued Mylan within the 45-day time period prescribed by the Hatch-Waxman Act, a 30-month regulatory stay of approval on Mylan's ANDA is required by the Act, which stay can terminate early only under certain specific circumstances. Anacor is merely following the statutorily-proscribed process here.

Anacor agrees with Mylan that if this Court enters a stay pending a decision by the PTAB, then there will be no need for a stay pending resolution of Anacor's JPML motion to transfer. *See* D.I. 39 at 5. But in the event this Court does *not* stay this case for the PTAB's decision, then Anacor stands by its in-the-alternative request for a stay until its JPML motion is decided. Mylan speculates that such a stay could result in "[a]n indefinite stay going beyond" the PTAB's resolution of the pending IPRs, but according to the JPML's own data, that is very unlikely to occur. *See, e.g.*, John G. Heyburn II, *A View from the Panel: Part of the Solution*, 82 Tulane L. Rev. 2225, 2242 (2008) (stating that "the average time between filing and decisions" is "about thirteen weeks" with a range of "between ten and seventeen weeks"). And it is Mylan, not Anacor, who has engaged in "manipulative forum shopping." D.I. 39 at 6. Fourteen ANDAs have been filed, and of those fourteen filers, Mylan is the *only* filer who has objected to venue in Delaware. It makes absolutely no sense for this case to proceed on its own in the Northern District of West Virginia, particularly when a transfer to Delaware would not affect Mylan's ability to continue to challenge the validity of the patents in its chosen forum: the PTAB.

Anacor's motion to transfer is simply intended to avoid a needless waste of resources by the parties and the judicial system—precisely what MDLs were designed to do.[2] *See, e.g.*, *In re Rosuvastatin Calcium Patent Litig.*, 560 F. Supp. 2d 1381, 1382 (J.P.M.L. 2008) (transferring Hatch-Waxman cases to the District of Delaware and observing that "[a]ctions involving the validity of complex pharmaceutical patents and the entry of generic versions of the patentholder's drugs are particularly well-suited for transfer under" the MDL statute).

CONCLUSION

For the foregoing reasons and for those set forth in Anacor's opening memorandum, Anacor respectfully requests that this Court grant Anacor's motion and enter a stay according to the terms Anacor has proposed.

Respectfully submitted,

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[2] Mylan suggests that Anacor somehow acted improperly by filing suit against Mylan in the District of Delaware less than two weeks after one district judge, in an unrelated patent infringement case, found that Mylan is not subject to venue in Delaware for the purpose of that litigation. *See* D.I. 39 at 6. Obviously, Anacor is not bound by that court's decision and is not obligated to assume that the same facts would apply in this case.

CERTIFICATE OF SERVICE

I hereby certify that on February 4, 2019, I caused a true and correct copy of the foregoing **REPLY IN SUPPORT OF ANACOR'S MOTION TO STAY CASE** to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record as follows:

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