

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BIOGEN INTERNATIONAL GMBH,

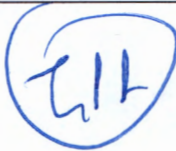
Plaintiff,

v.

BANNER LIFE SCIENCES LLC,

Defendant.

C.A. No. 18-2054-LPS



**PROPOSED FINAL JUDGMENT AND LIMITED  
TEMPORARY RESTRAINING ORDER**

Pursuant to the Court's Memorandum Opinion and Order (D.I. 52, 53) of January 7, 2020, granting Banner's Motion for Judgment on the Pleadings, and the Court having considered the parties' positions in the Joint Status Report dated January 13, 2020 (D.I. 55) and in a joint teleconference on January 17, 2020, and for the reasons stated on the record during that teleconference and in the Court's January 21, 2020 Order, it is hereby ORDERED and ADJUDGED that:

1. Final Judgment of non-infringement is entered on behalf of Defendant Banner Life Sciences ("Banner") with regard to its counterclaim and against Plaintiff Biogen International GmbH's ("Biogen") claim of infringement regarding all claims of U.S. Patent No. 7,619,001 for the reasons stated in the Court's Memorandum Opinion of January 7, 2020.
2. Defendant is the prevailing party as to Plaintiff's claims of infringement of U.S. Patent No. 7,619,001 and as to Defendant's counterclaims for declaratory judgment of noninfringement of U.S. Patent No. 7,619,001.

3. Any motion for an award of costs or attorneys' fees shall be deferred until all appeals relating to this litigation have been exhausted and the Mandate has issued from the Court of Appeals. If Plaintiff does not file an appeal in this litigation, Defendant's deadline for filing such motions and their bills of costs shall be extended to 45 days after the deadline for Plaintiff to file an appeal has lapsed.

4. After this Court rendered its January 7, 2020, Memorandum Opinion finding that Banner did not infringe, Biogen orally requested on January 17 either a Temporary Restraining Order or an Injunction pending appeal. Having considered the premises and the arguments of the parties, and for the reasons stated on the record at the teleconference of January 17, 2020, this Court denies Biogen's motion for an injunction pending appeal but grants a limited Temporary Restraining Order.

5. To allow Biogen time to pursue an injunction pending appeal from the Court of Appeals for the Federal Circuit, Banner is enjoined from launching the product that is the subject of its NDA No. 210296 prior to the expiration of this Temporary Restraining Order.

6. For the avoidance of doubt, this Temporary Restraining Order will not prohibit the FDA from finally approving Banner's NDA No. 210296 should the FDA determine that the NDA has otherwise satisfied the conditions of final approval.

7. Nor does this Temporary Restraining Order prohibit Banner from engaging in pre-launch activities such as manufacturing or stocking product in warehouses. This Temporary Restraining Order does prohibit Banner from selling or offering for sale the product that is the subject of its NDA No. 210296.

8. This Temporary Restraining Order will expire on the earlier of (a) February 4, 2020 at 10:00 a.m. Eastern Standard Time or (b) a decision from the Federal Circuit denying any motion for an injunction during the pendency of any appeal.

9. Additionally, this limited Temporary Restraining Order is expressly conditioned on Biogen's compliance with the following terms, all of which the Court deems reasonable and appropriate to preserve the status quo for (at most) until February 4, 2020 at 10:00 a.m. Eastern Standard Time:

(i) Biogen will move to expedite its appeal in the Federal Circuit. Biogen agrees that it will file its motion for relief before the Federal Circuit with all deliberate speed and that Banner can expedite its opposition as it deems appropriate;

(ii) Biogen shall not take any steps or actions to delay or inhibit final approval of Banner's NDA product;

(iii) Biogen agrees to provide security in the form of a corporate undertaking during the pendency of this Temporary Restraining Order in the amount of \$ ~~SEE~~ <sup>\$30,000,000.00</sup> BELOW, pursuant to Fed. R. Civ. P. 65(c) to cover proven damages, if any, to the extent that Banner proves damages in a later proceeding.

LPR

Biogen's Proposal

The standard should not be what Biogen currently is earning on its longstanding, well-established, market-leading product, but rather, is the *profit* that Banner realistically could earn in the next 13 days on a product which is not substitutable for Tecfidera, for which it still needs to secure final FDA approval, will be trying to enter a crowded field of competing products, does not yet have any established market relationships or distribution channels, and does not yet have any ongoing marketing, name recognition, or foothold in the medical community. Even assuming a very reasonable profit margin of 14%, a new entrant, without published favorable clinical trial results, just starting the ramping-up process, cannot be expected to make \$30 million in just the next 13 days, nor capture much more than a small percent of the market in 13 days and certainly not the significant percent of Tecfidera revenue which is the amount Banner's proposal represents. Biogen respectfully submits that \$300,000 is more than reasonable security under these circumstances.

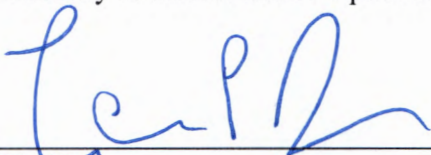
Regarding Banner's protestations about timing, Biogen also apologizes to the Court for the late filing. However, we did not receive Banner's revised proposal (from \$50 million to \$30 million) until 7:43 p.m., and until that point we assumed that they were working on a very brief explanation of their position just as we were. We hope the Court will find the short explanations helpful for the Court's evaluation.

**Banner's Proposal**

Banner's proposal is \$30,000,000. First, Banner apologizes for this submission getting in after the Court ordered deadline of 8 p.m. ET. Biogen stated that it would send a proposed form of order for Banner's review. It did not do so. Banner then sent a proposed order inserting the amounts (which is all it understood the Court to be requesting) to Biogen. At 7:59 p.m., Biogen finally responded and for the first time inserted its "Proposal" language. Banner did not understand the Court to be requesting further briefing, and thus, thinks the Court can determine reasonableness. But, given Banner's receipt of new information from Biogen at 7:59 p.m., obviously Banner was put in the position of being unable to meet the Court's deadline, and Banner apologizes to the Court.

Nevertheless, by way of brief explanation, as the Court noted, in roughly 2 weeks, Biogen will make approximately \$125 million in U.S. sales for Tecfidera® (with worldwide sales being closer to \$170 million). Banner believes its product can compete effectively with Tecfidera and believes that \$30 million over two weeks is an appropriate amount for security. Of course, Banner can only ultimately recover what it can actually show it suffers in damages should the TRO have been wrongly entered. This is not the time to decide that issue. Rather, the issue is, assuming Banner can later show losses, what should be the cap on those losses? Clearly, Biogen's proposed \$300,000 is insufficient security to offset Banner's potential losses during the TRO.

January 21, 2020



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Chief Judge