

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 22-615 (MN)
	)	(CONSOLIDATED)
LUPIN LTD., LAURUS LABS LIMITED,	)	
and CIPLA LIMITED,	)	
	)	
Defendants.	)	

PLAINTIFF GILEAD SCIENCES, INC.'S FINAL VALIDITY CONTENTIONS

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VI. The Asserted Claims of the '802 Patent Are Not Invalid⁵

Gilead asserts claims 1–13 of the '802 patent against one or more Defendants.

A. Claim Construction

The parties presently agree that all claim terms of the '802 patent should receive their plain and ordinary meaning, and do not presently disagree about the construction of any term of the '802 patent. Plaintiff reserves all rights to modify its proposed constructions as the case proceeds.

B. The Asserted Claims Are Not Anticipated by WO '116

Defendants separately argue that the asserted claims of the '802 patent are anticipated by WO '116. Defendants' Final Invalidity Contentions (July 2, 2024) at 480–482. The asserted claims are not anticipated by WO '116 because WO '116 is not prior art to the '802 patent. WO 2015/169116 ("WO '116") is a published international application corresponding to the '342 and '067 patents. WO '116 has a publication date of Dec. 23, 2015. The '802 patent is entitled to a priority date corresponding to the filing of U.S. Prov. App. No. 62/253,042 (filed Nov. 9, 2015). As the Patent Office found during prosecution of the '802 patent, WO '116 was published after the effective filing date of the application that led to the '802 patent. *See* April 17, 2023 Notice of Allowance. Therefore, as the Patent Office found, WO '116 is not an invalidating reference.

C. The Asserted Claims Are Not Obvious

The above discussions of obviousness with respect to the '342, '067, and '846 patents are incorporated herein by reference as if set forth in their entirety. Defendants' invalidity contentions list 37 purported obviousness combinations (some of which are combinations of combinations), and provide little additional analysis of specific combinations. *See* Defendants' Final Invalidity

⁵ Many of Defendants' arguments that claims of the '802 patent are invalid overlap with Defendants' arguments that claims of the '846 patent are invalid. Gilead incorporates by reference all arguments made in support of the validity of the '846 patent into this section and each argument applies with equal weight to the '802 patent.

Contentions (July 2, 2024) at 483–485. At least WO '116, WO '323, WO '351, and NCT '694 are art of record which appear on the face of the '802 patent. Similarly, the claim chart accompanying Defendants' Final Invalidity Contentions lists quotes and excerpts from various alleged prior art references without any further analysis of the significance of those quotes and excerpts, or of which particular combinations allegedly render obvious the asserted claims. *See generally* Defendants' Final Invalidity Contentions, App'x D. In certain instances, the claim chart accompanying Defendants' Final Invalidity Contentions simply provides a string citation to a list of alleged prior art references, without *any* further disclosure analysis of what the references allegedly teach, or even which portion of the references Defendants purport to rely on. *See e.g. Id.* at 27, 43, 55, 81, 97, 123, 139 (among others).

Defendants identify two specific references, NCT '694 and WO '116, which Defendants acknowledge were not publicly available under after November 9, 2015. Defendants' Final Invalidity Contentions (July 2, 2024) at 113–117. As explained above, these references are therefore not prior art to the '846 and '802 patents, and all citations to or reliance on them by Defendants should be disregarded.

As non-limiting examples, the asserted claims of the '802 patent are not obvious over combinations of references relying on WO '323, at least because a POSA would not have been motivated to select bictegravir for further development from among the more than 80 molecules recited in claims 31 and 32. Similarly, the asserted claims of the '846 patent are not obvious over combinations of references relying on US '356, at least because a POSA would not have been motivated to select bictegravir for further development from among the more than 80 molecules recited in claims 31 and 32. The asserted claims of the '802 patent are also not obvious over combinations relying on the '385 patent or other references disclosing known INSTI structures.

Based on the disclosure of prior art INSTI molecules, it would not have been obvious to a POSA to modify stereochemistry, modify a difluorobenzyl tail (or other benzyl tail structure) to a trifluorobenzyl tail, and/or to modify the ring structure to a bridged bicyclic ring, never mind to make all of these modifications simultaneously. And a POSA would not have had any reasonable expectation of success in making any of these modifications in isolation, never mind in making all of them simultaneously.

Further, for at least the reasons discussed above in connection with alleged obviousness-type double patenting of the '846 patent, the asserted claims of the '802 patent are not obvious over any of Defendants' asserted combinations because Defendants identify no prior art that teaches or suggests administering a dose of 50 mg of bictegrovir when co-formulated in a tablet with tenofovir alafenamide and emtricitabine. A POSA would understand that the existing prior art in fact taught away from this dosing. As described above, Defendants' purported motivations for a POSA to select this dose are incorrect and based on hindsight. A POSA would not have been motivated to select or develop a dose of 50 mg of bictegrovir.

Defendants' Final Invalidity Contentions insert additional citations to a variety of additional alleged prior art references (including at least Walmsley, Weller, Castagna, Johns, PR, Mathais, Min, Highleyman, US '356, WO '351, US '332, Berge, Serajuddin, Paulekuhn, Remington 21st, Wells, and Bowker) without any specific explanation or analysis of what these references allegedly disclose. Defendants' Final Invalidity Contentions (July 2, 2024) at 506, 508, 518 (among others). If Defendants later identify specific teachings of these references that are allegedly relevant to Defendants' Invalidity Contentions, Plaintiff reserves all rights to respond.

D. The Asserted Claims Are Not Invalid for Obviousness-Type Double Patenting over the '067 Patent

The above discussion of obviousness-type double patenting of the '846 patent over the '067 patent and over the '342 patent is incorporated by reference as if set forth in its entirety. See *supra* at V.B–.C. The '067 patent is art of record that appears on the face of the '802 patent. The '067 patent and the '342 patent share the same specification. The claims of the '067 patent do not disclose a 50 mg dose of bictegavir, and a 50 mg dose of bictegavir is not obvious over the claims of the '067 patent in combination with the specification of the '067 patent or any other reference. Like the '846 patent, the claims of the '802 patent are directed to a tablet comprising 50 mg of bictegavir or a pharmaceutically acceptable salt thereof. See '802 patent at 77:27–78:4 (independent claim 1). For at least the reasons set forth above, the '802 patent is not invalid for obviousness-type double patenting over the '067 patent.

E. The Asserted Claims Are Not Invalid for Obviousness-Type Double Patenting over the '342 Patent

The above discussion of obviousness-type double patenting of the '846 patent over the '067 patent and over the '342 patent is incorporated by reference as if set forth in its entirety. See *supra* at V.B–.C. The '342 patent is art of record that appears on the face of the '802 patent. The '067 patent and the '342 patent share the same specification. Like the '067 patent, the claims of the '342 patent do not disclose a 50 mg dose of bictegavir, and a 50 mg dose of bictegavir is not obvious over the claims of the '342 patent in combination with the specification of the '342 patent or any other reference. Like the '846 patent, the claims of the '802 patent are directed to a tablet comprising 50 mg of bictegavir or a pharmaceutically acceptable salt thereof. See '802 patent at 77:27–78:4 (independent claim 1). For at least the reasons set forth above, the '802 patent is not invalid for obviousness-type double patenting over the '342 patent.

F. Objective Indicia Support Non-Obviousness

The non-obvious of the asserted claims of the '802 patent is supported by objective indicia of non-obviousness for at least the same reasons as the asserted claims of the '846 patent. The above discussion of objective indicia of non-obviousness with respect to the '846 patent is incorporated by reference. *See supra* at V.D.

The non-obviousness of the asserted claims of the '802 patent is supported by at least the commercial success of Biktarvy®, which has a nexus to the asserted claims of the '802 patent. The '802 patent describes and claims the tablet formulation and dosages that are in fact reflected in the Biktarvy® commercial product, and the claims of the '802 patent thus have a clear nexus to the commercial success of Biktarvy®.

Unexpected results also support the non-obviousness of the asserted claims of the '802 patent. The above discussion of unexpected results regarding the '846 patent is incorporated by reference as if set forth in its entirety. *See supra* at V.D. As discussed above, it would have been highly unexpected to a POSA (and was in fact unexpected to Gilead) that a 50 mg dose of bictegravir, when co-formulated with tenofovir alafenamide and emtricitabine, would be a therapeutically effective amount of bictegravir for the treatment of HIV.

G. The Asserted Claims Are Not Invalid Under § 112

The asserted claims of the '802 patent are not invalid for lack of enablement or written description for at least the same reasons as the claims of the '846 patent. The above discussion of enablement and written description with respect to the '846 patent is incorporated by reference. *See supra* at V.G.

Defendants further contend that the asserted claims of the '802 patent are invalid because they fail to disclose the full scope of the claimed “tablet.” Defendants’ Final Invalidity Contentions (July 2, 2024) at 599. Defendants provide a list of types of tablets, but fail to explain which (if

any) of these tablets are allegedly not described or enabled. “Tablets” are a category of “solid oral dosage forms.” ’802 patent at 4:33–36. The ’802 patent provides extensive disclosure regarding the various characteristics of tablets and aspects that a person of skill in the art would consider in formulating them. For example, the specification provides extensive discussion of suitable excipients, including external references. *Id.* at 13:3–14:27. The specification likewise provides extensive disclosure regarding other formulation considerations such as coating (*id.* at 14:28–56) and manufacturing methods (*id.* at 53:54–54:46). These teachings (among others), in combination with the knowledge and skill of a person of skill in the art, are amply sufficient to describe and enable the full scope of the asserted claims.

VII. Reservation of Rights

This response is based on information that Gilead has at this stage of the litigation. Gilead reserves the right to supplement this response and/or serve Validity Contentions as more information becomes available to Gilead through discovery, including but not limited to additional produced documents, depositions, interrogatory responses, request for admission responses, and sample testing. This response includes citations to certain illustrative supporting evidence. This evidence is merely exemplary and intended to provide notice of where Defendants allegations of invalidity are deficient. Gilead reserves the right to rely on additional evidence to support its validity contentions and claims.

Discovery is ongoing. Gilead reserves the right to supplement or revise its Interrogatory responses in accordance with the Federal Rules of Civil Procedure and the Local Rules of the District of Delaware. Gilead expressly reserves the right to amend, supplement, or otherwise modify this response as additional information becomes available during discovery and as further investigation and analysis is performed. Gilead explicitly reserves the right to file Final Validity Contentions as provided for by the Scheduling Order.

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August 2, 2024

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CERTIFICATE OF SERVICE

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