

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PF PRISM C.V., PFIZER PFE
IRELAND PHARMACEUTICALS
HOLDING 1 B.V., and PFIZER
MANUFACTURING HOLDINGS LLC,

Plaintiffs,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants.

Civil Action No. 1:18-cv-00795-RGA

MEMORANDUM ORDER

This memorandum order reflects and memorializes the decisions I made during the Markman hearing in this case. I have considered the Parties' Joint Claim Construction Brief (D.I. 51). I heard oral argument, and resolved the Parties' disputes, on June 24, 2019.

The Parties sought construction of three terms in U.S. Patent No. 8,791,140 ("140 Patent"). Specifically, the Parties disputed terms that appear in exemplary claims 1 and 5:

1. *A crystalline form of 6-[2-(methylcarbamoyl)phenylsulfanyl]-3-E-[2-(pyridin-2-yl)ethenyl]indazole, wherein said crystalline form has a powder X-ray diffraction pattern comprising a peak at diffraction angle (2θ) of 6.0 ± 0.1 and further comprising at least one peak at diffraction angle (2θ) selected from 11.5 ± 0.1 , 21.0 ± 0.1 and 26.9 ± 0.1 .*

5. *A crystalline form of 6-[2-(methylcarbamoyl)phenylsulfanyl]-3-E-[2-(pyridin-2-yl)ethenyl]indazole, wherein said crystalline form has a solid state NMR spectrum comprising ^{13}C chemical shifts at 150.1 ± 0.2 , 136.6 ± 0.2 , 135 ± 0.2 , 116.9 ± 0.2 and 27.5 ± 0.2 ppm.*

('140 Patent, claims 1,5 (disputed terms italicized)).

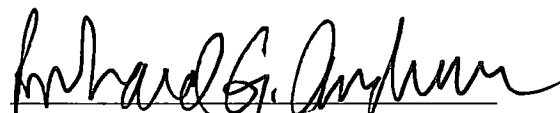
On the “crystalline form” term, I ruled that the Applicant disclaimed forms of 6-[2-(methylcarbamoyl)phenylsulfanyl]-3-E-[2-(pyridin-2-yl)ethenyl]indazole (“axitinib”) other than Form XLI. When faced with a restriction requirement, the applicant chose to pursue Form XLI. (D.I. 35, Exh. 4 at 4). Later, when the examiner required the applicant to claim Form XLI more specifically, the applicant selected the claimed peaks and chemical shifts as the identifying characteristics of the Form. (D.I. 35, Exh. 6 at 8; *see also* D.I. 35, Ex. 5 at 10 (examiner’s rejection and suggestion that the applicant claim Form XLI with reference to the compound’s chemical nature)). That is, the applicant represented to the examiner, and the public, that an axitinib crystal that produces the claimed peaks is Form XLI.

The Parties agreed at oral argument that Form XLI is the claimed invention. They didn’t even seriously dispute that only Form XLI, and not some other Form of axitinib, produces the claimed peaks and chemical shifts. Thus, it is reasonable to say that Form XLI is defined by the claimed peaks. In order to prove infringement, Plaintiffs need only prove that the accused substance produces the claimed peaks or chemical shifts. Plaintiffs are not, however, required to separately prove, presumably by some other technique, that the substance is Form XLI. Thus, I ruled that “crystalline form” has its plain and ordinary meaning.

On the “peak” and “¹³C chemical shift” terms, I ruled that, on the record presented to me, Defendants have not proven indefiniteness by clear and convincing evidence. Accordingly, I construed “peak” and “¹³C chemical shift” as having their plain and ordinary meanings. Although Defendants argued that the plain and ordinary meaning does not clarify the terms in the context of the patent, they did not disagree that the terms, outside the patent, generally have the plain meanings proposed by Plaintiffs. (D.I. 51 at 47, 68). Thus, I found that the plain and ordinary meaning of “peak” is “a signal that is discernible from the noise” and the plain and

ordinary meaning of “¹³C chemical shift” is “signal in the solid-state NMR spectrum that is discernible from the noise.”

IT IS SO ORDERED this 20th day of June 2019.


United States District Judge