

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

ABBVIE INC., et al.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD., et
al.,

Defendants.

C.A. No. 20-968 (MSG)
(Consolidated)

ABBVIE INC., et al.,

Plaintiffs,

v.

ALEMBIC PHARMACEUTICALS LTD.,
ALEMBIC PHARMACEUTICALS, INC.,
and ALEMBIC GLOBAL HOLDING SA,

Defendants.

C.A. No. 20-1009 (MSG)

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

AbbVie and Genentech (“Plaintiffs”) invented and market Venclexta[®], a groundbreaking “orphan drug”¹ for treatment of chronic lymphocytic leukemia (“CLL”), small lymphocytic lymphoma (“SLL”), and acute myeloid leukemia (“AML”). *See, e.g.*, Ex. 1 at 1; Ex. 2 at 1-6.² CLL and SLL are blood cancers that progress until “morbidity is considerable, both from the disease and from complications of therapy.” *See, e.g.*, Ex. 3 at 1, 4-5. AML is “one of the most aggressive blood cancers, with a very low survival rate,” attacking with such speed that it affords few options for some patients to receive treatment before the introduction of Venclexta. *See, e.g.*, Ex. 4 at 1.

Plaintiffs filed these patent infringement cases under the Hatch-Waxman Act in response to Defendants’ Abbreviated New Drug Applications, which seek approval to market generic versions of Venclexta[®]. The lawsuits involve three patent families: (1) a family covering the active ingredient in Venclexta[®] (a compound known as “venetoclax”) and methods of use thereof; (2) a family covering certain crystalline forms, or “polymorphs,” of venetoclax; and (3) a family covering dosing/administration of venetoclax. This claim construction proceeding includes terms only from the three related patents within the second “polymorphs” family.

Defendants have collectively identified five terms for construction, which implicate similar claim construction issues. These terms concern venetoclax crystalline forms with powder X-ray diffraction (“PXRD”) patterns having a recited number of peaks. PXRD, as described

¹ An orphan drug is “used to treat, prevent, or diagnose an orphan disease. An orphan disease is a rare disease or condition that affects fewer than 200,000 people in the United States. Orphan diseases are often serious or life threatening.” *See Definition of Orphan Drug, NCI Dictionary of Cancer Terms*, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/orphan-drug> (last visited Apr. 7, 2022).

² “Ex. _” refers to exhibits submitted with Plaintiffs’ Opening Claim Construction Brief.

more fully below, is an analytical technique used, *inter alia*, to determine the crystal structure of materials of interest.

The claims at issue require the presence of a certain number of recited peaks and are clear on their face. Defendants' proposed constructions add an additional test requiring the PXRD patterns to "correspond[] to" certain exemplary patterns from the patent specification. Defendants' additional test violates well-established claim construction principles against importing limitations into the claims and is inconsistent with the express language of the claims. Moreover, Defendants' new test introduces ambiguity and conflict to the claims, as it is unclear how to determine whether one pattern "corresponds to" another. For example, must the patterns have all of the same peaks, half of them, or satisfy some other metric to "correspond to" each other?

The claims themselves inform a person of ordinary skill in the art of exactly what is required without introducing Defendants' new test into the analysis. As such, Plaintiffs submit that there is no need to construe these readily understood claim terms. In light of Defendants' term identifications and proposed constructions, however, Plaintiffs offer alternative constructions reflecting the plain and ordinary meaning of these terms.

II. BACKGROUND

Venclexta[®] is protected by several patents, including the three patents at issue in claim construction: U.S. Patent Nos. 8,722,657 ("the '657 patent"), 9,238,649 ("the '649 patent"), and 10,730,873 ("the '873 patent") ("the asserted polymorph patents"). Claim 1 of the '657 patent, claim 1 of the '649 patent, and claim 4 of the '873 patent are representative of the claim language at issue here and are copied below with the disputed claim terms emphasized.

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