UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: TASIGNA (NILOTINIB)
PRODUCTS LIABILITY LITIGATION

Case No. 6:21-md-3006-RBD-DAB
(MDL No. 3006)

This document relates to all actions.

ORDER

This matter comes before the Court on Plaintiffs' Motion to Compel Production (doc. no. 84) of documents related to certain clinical trials involving Tasigna. There is no dispute as to most of the clinical trial information. However, with respect to trials related to Tasigna used for treatments not related to chronic myeloid leukemia ("CML"), Novartis objects. Broadly speaking, Plaintiffs need clinical trial information to support their claims of causation failure to warn and negligence. Plaintiffs argue that the medical indication involved in these trials does not affect the pertinence of safety data.

Novartis objects to supplying this additional information largely on grounds of burden and the cumulative nature of the information.

Based on the written and oral presentations, the Court concludes that the burden of producing information related to the non-CML trial is *de minimis*. While the marginal utility of the information, given what has been made available to Plaintiffs, may not be great, they are entitled to it.

A second issue is presented in the motion: the raw data sets for 38 clinical trials. Plaintiffs assert that their expert witness needs access to the raw data to be able to perform certain analyses.[1] Novartis questions whether such information is needed for expert analysis and again asserts that *any* burden of production is too much, as it would be cumulative. As with the non-CML nature of the information about the trials, the Court finds these arguments unavailing. The burden of production is small, and it is for Plaintiffs and their expert to determine what use they need to make of available data, subject ultimately to cross examination. Subject to the following exceptions, therefore, the motion is **GRANTED**, in part.

Novartis also raises objections to particular categories of the studies: six of the trials are on-going; another 18 of the studies involve non-US patients and are subject to different privacy rules; and 7 of the trials are from third parties.

The Court agrees that it would not be appropriate to disclose data from on-going studies. Partial results from incomplete studies may be misleading and certainly are too indefinite a basis for a scientific analysis. Moreover, premature disclosure could undermine the protocols of the trials themselves. The motion is **DENIED** as to these studies.

Privacy issues with respect to foreign patients are matters which should be

[1] This is not to say that the expert necessarily will offer opinions in this case based on such analyses, but he wants access to be able determine what opinions may be drawn consistent with the standards for expert testimony and the needs of the case.

adequately covered by the parties' confidentiality agreement. To the extent the laws of another country require something more, the parties are directed to make such further provisions as may be necessary. Subject to that caveat, the motion is **GRANTED** as to the foreign patient trials.

As to third party trials or studies, simply stated, Novartis cannot be compelled to produce what it does not itself have (or have access to). Plaintiffs have not demonstrated that data from these third party trials is within Novartis' control, so the motion is **DENIED** in this regard.

DONE and **ORDERED** in Orlando, Florida, on March 15, 2022.

David A. Baker

DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE

Copies furnished to:

Counsel of Record