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Client Alert

Corporate Practice Group

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SRS vs. Gilead Sciences: Delaware Chancery Court finding that "indication" means "disease" allows Gilead not to make $50M Milestone Payment

In *Shareholder Representative Services (SRS) vs. Gilead Sciences et al.*, an opinion issued on March 15, 2017, the Chancery Court of the State of Delaware found that the term "indication" means "disease" for purposes of a $50M contingent milestone payment in a merger agreement between buyer Gilead Sciences, Inc. ("Gilead") and Calistoga Pharmaceuticals, Inc. ("Calistoga"). As a result, the regulatory approval that Gilead obtained for treating chronic lymphocytic leukemia ("CLL") patients with a particular biomarker did not trigger the $50M contingent milestone payment because such regulatory approval was for a "subpopulation of people suffering from a disease" and was not a "disease-level [regulatory] approval".

Background

On February 21, 2011, Gilead and Calistoga executed an Agreement and Plan of Merger ("Merger Agreement") pursuant to which Gilead acquired Calistoga. Plaintiff Shareholder Representative Services LLC ("SRS") was appointed as the agent for the former securityholders of Calistoga. The Merger Agreement contained a $50M contingent milestone payment that would become due after the earliest to occur of the following:

> (A) the receipt of Regulatory Approval of CAL-101[i] in the United States or the European Union, whichever occurs first, for a solid tumor indication, (B) the receipt of Regulatory Approval of CAL-101in the United States or the European Union . . . ***as a first-line drug treatment (i.e., a treatment for patients that have not previously undergone systemic drug therapy therefor) for a Hematologic Cancer Indication***, or (C) Annual Net Sales of CAL-101 achieving at least $1 Billion, so long as such Annual Net Sales are achieved on or before the first day of the first calendar quarter beginning after the [tenth (10th) anniversary of the Closing Date].

The term "Hematologic Cancer Indication" was defined in the Merger Agreement as "[a]ny ***indication*** within the following tumor types," and

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listed a series of blood cancers such as neoplasms, lymphomas, and leukemias, including CLL.

On September 14, 2014, Gilead received the following regulatory approval from the European Commission for CAL-101:

> Zydelig is indicated in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL):
>
> - who have received at least one prior therapy, or
> - ***as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy***.

SRS alleged that the approval of Zydelig for patients with CLL "as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy" satisfied the milestone event of "Regulatory Approval of CAL-101 in the United States or the European Union . . . as a first-line drug treatment (i.e., a treatment for patients that have not previously undergone systemic drug therapy therefor) for a Hematologic Cancer Indication", and thereby triggered the $50M contingent milestone payment. Gilead disagreed; on July 14, 2015, SRS filed a complaint against Gilead and one of its subsidiaries for failure to pay the $50M contingent milestone.

Opinion of the Chancery Court of the State of Delaware

SRS argued that the term "indication", used in the definition of "Hematologic Cancer Indications" to trigger the $50M milestone payment, means "the approved use of a drug in a population of patients with a particular disease." Gilead argued that "indication" means "a disease".

The Court found that the term "indication" was ambiguous as used in the Merger Agreement and therefore permitted the consideration of extrinsic evidence to determine what the parties intended "indication" to mean. In making its determination that the meaning of "indication" was ambiguous, the Court found that the term "indication" could not be defined within the four corners of the Merger Agreement and cited statements by witnesses for both Gilead and SRS that indication could refer to a "disease," a "tumor," "an indication for starting treatment in a patient," or "a regulatory approval."

In determining what the parties intended for the term "indication" to mean under the Merger Agreement, the Court looked to the negotiating history of the parties. In particular, the Court noted that the list of hematologic cancer indications listed in Section 1.1 of the "Hematologic Cancer Indication" definition was provided by Calistoga and was derived from the top level categories of diseases in the World Health Organization Classification. The Court also cited the fact that SRS used the term "indication" to mean "diseases" in some of the presentations and regulatory materials it sent to Gilead during negotiations, and that communications between SRS and Gilead after the regulatory approval showed that both parties used the term "indication" to mean "disease".

The Court also pointed to the three subparts of the milestone each of which could trigger the $50M contingent milestone payment because, according to testimony, each subpart was "intended to recognize value inflections

that could lead to significant commercial reward." The Court stated that the commercial value of the first subpart (*i.e.*, approval for treatment of a solid tumor) would be "highly valuable" because it would expand the drug's use to a "completely different class and universe of cancers" and that the value of the third subpart of the milestone (*i.e.*, "Annual Net Sales of CAL-101 achieving at least $1 Billion") was "self-evident." The Court stated that the "first-line" milestone trigger in question, like the other two triggers, also "was intended to reward an event of significant commercial success." The regulatory approval in question fell short of this significant commercial success, the Court concluded, in part because "there are genetic mutations within CLL that are present in only 0.44% of CLL patients". And, under SRS's reasoning, Gilead would be obligated to pay the milestone even if it received regulatory approval for that very small sub-population of CLL patients.[ii]

Significance of *SRS v. Gilead*

The Court's reliance on the parties' expected "commercial value" of the regulatory approval that would obligate Gilead to pay SRS the $50M contingent milestone, as revealed by the negotiating history, was central to the Court's analysis and conclusion. In the context of that negotiating history, the Court also looked to the commercial value represented by the two *other* potential triggering events for payment of this milestone – *i.e.*, approval in the entirely different field of solid tumors, or the achievement of annual sales of at least $1 Billion – and concluded that the triggering event at issue, which required achieving regulatory approval as a first-line treatment in an "indication" within a list of specified hematologic tumor types (including CLL), was not met by receiving regulatory approval for a *sub-population* of CLL patients. Because of the parties' expectation that the commercial success for the "front-line" regulatory approval milestone would be comparable to the other two milestone payment triggers, the Court found that Gilead should not be obligated to pay $50M to SRS for a regulatory approval that was not "disease-level".

SRS v. Gilead also merits attention because the biopharma industry is increasingly pursuing narrower regulatory approvals. Especially in the oncology field, identifying patient subpopulations that can most benefit from a therapy increases the likelihood of regulatory approval. This approach to drug development is part of what is known as "precision medicine," which hold promise for better patient outcomes. However, the Court's conclusion in *SRS v. Gilead* that regulatory approval in an "indication" refers to a "disease-level" approval, rather than approval in a sub-population of patients with the diseases, merits attention, and when structuring and drafting deals involving contingent milestone payments triggered by regulatory approval – especially when the parties anticipate seeking narrower regulatory approval in patient subpopulations – companies should consider including a definition of indication in transaction agreements to avoid the possibility of an issue like the one the Court addressed in *SRS v. Gilead*.

[i] CAL-101 (*Zydelig*; Idelalisib) is a small molecule drug developed by Calistoga and, after the acquisition, by Gilead for the treatment of hematological cancers.

[ii] The Court's opinion, however, made no reference to any finding or evidence regarding the percentage of CLL patients that have the 17p deletion or TP53 mutation specified in the regulatory approval at issue.