Saiber Helps Several Viatris and Mylan Entities Successfully Dismiss Patent Infringement Claims, Transfer Remaining Action Due to Improper Venue in District of New Jersey

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Along with lead co-counsel Wilson Sonsini Goodrich & Rosati, Saiber attorneys Arnold B. Calmann, Jakob B. Halpern and Catherine Soliman recently obtained dismissal of patent infringement claims asserted in the United States District Court for the District of New Jersey by plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. ("Plaintiffs") against clients Viatris Inc. ("Viatris"), Mylan Inc., Mylan API US LLC ("Mylan API"), Mylan Laboratories Ltd. ("MLL"), and Agila Specialties Inc. ("Agila"). Moreover, based on defendants' arguments and applying the patent venue statute, the Court determined that venue in the District of New Jersey over the remaining defendant, Mylan Pharmaceuticals Inc. ("MPI"), was improper and transferred the action to the Northern District of West Virginia.

Plaintiffs had alleged the filing of an Abbreviated New Drug Application ("ANDA") to market generic versions of plaintiff Salix's plecanatide oral tablets product, Trulance®, constituted patent infringement. In moving to dismiss, defendants argued that, as the ANDA submitter, only MPI could be liable under the Hatch-Waxman Act for patent infringement – meaning the other defendants should all be dismissed – and that venue in the District of New Jersey was improper as to most of the defendants under 28 U.S.C. section 1400, the patent venue statute. The district court, through the Hon. Stanley R. Chesler, agreed.

The Court first agreed with defendants' venue arguments. Under the patent venue statute, venue is proper only where the defendant resides or where it has a "regular and established place of business." Judge Chesler determined that MPI alone prepared and electronically submitted the ANDA, with those actions all occurring outside of New Jersey. Moreover, Judge Chesler determined that Plaintiffs not only failed to properly allege that MPI had a "regular and established place of business" in New Jersey, but also that "Plaintiffs [did not] present factual allegations sufficient to find that [venue] discovery is warranted." In doing so, the Court rejected a number of arguments by Plaintiffs on the subject, including that, for instance, several employees of various defendants resided in New Jersey; some defendants have been involved in the conduct of clinical trials in New Jersey; several defendants are registered with the New Jersey Department of Health and/or were licensed in New Jersey; some defendants made payments in and derived revenue from New Jersey; and defendants have conducted litigation in New Jersey. Judge Chesler concluded that none of these activities constituted a "regular and established place of business" in New Jersey.

Second, the Court determined that Plaintiffs failed to state a viable claim against two additional defendants because they were not "submitters" of the ANDA and thus were not properly alleged to have infringed the patents. Judge Chesler observed that the only way potential liability could

attach were if these entities were actively involved in preparing the ANDA, but held that there was nothing beyond Plaintiffs' conclusory allegations to that end and that any potential amendment would be futile.

Following the Court's rulings, only Plaintiffs' patent infringement claims against MPI remained, and, in the interest of justice, it exercised its discretion to transfer those claims to the Northern District of West Virginia rather than dismiss them.