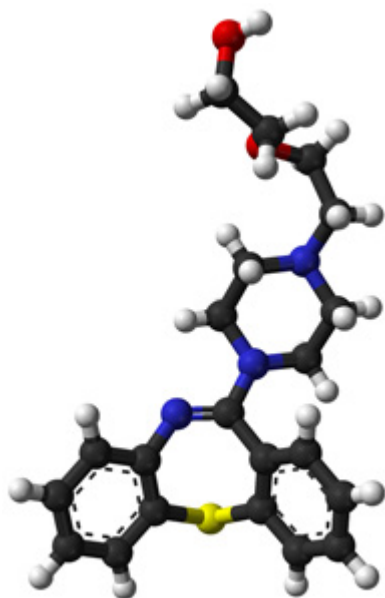


Hatch-Waxman Watch: AstraZeneca Pharmaceutical LP v. Intellipharmaeconomics Corp. (D.N.J. 2012)

By Andrew Williams -- February 23, 2012



Last week, in *AstraZeneca Pharmaceutical LP v. Intellipharmaeconomics Corp.*, Civil Action No. 11-2973 (JAP), Judge Pisano of the U.S. District Court for the District of New Jersey dismissed a Hatch-Waxman Act patent infringement action based on a lack of personal jurisdiction because the ANDA filer did not have the requisite minimum contacts with the state to establish either general or specific jurisdiction. In this particular case, AstraZeneca Pharmaceutical LP and AstraZeneca UK Limited (together, "Astra") had filed suit against Intellipharmaeconomics Corp. ("IPC") and Intellipharmaeconomics International Inc. ("IPCI") in New Jersey because IPC had filed an ANDA to seek approval to market a generic version of Astra's Seroquel XR product. Both IPC and IPCI are Canadian companies. IPC and IPCI subsequently filed their motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(2) (lack of personal jurisdiction), or in the alternative, pursuant to 28 U.S.C. § 1406(a) to transfer to the Southern District of New York. Astra followed-up by also filing suit in New York to preserve its right to the statutory 30-month stay, but that action was stayed pending the outcome in the New Jersey Court.



For those readers who have not had the pleasure of a first-year Civil Procedure course, due process requires that a defendant have minimum contacts with a state before that state can exercise jurisdiction over them. This is because "traditional notions of fair play and substantial justice" prevent a plaintiff from hauling a defendant to court in a state in which that defendant does not have at least minimum contacts. There are two types of jurisdiction -- (1) general jurisdiction, in which the defendant has "continuous and systematic" contacts with a state such that a court can exercise jurisdiction for any action, and (2) specific jurisdiction, for cases in which general jurisdiction cannot be established, but there are sufficient limited contacts with the state that relate to the claims of the suit.

In the present case, the Judge first looked to whether IPC and IPCI were subject to general jurisdiction in New Jersey. Astra had claimed that IPC and IPCI had continuous and systematic contacts with New Jersey because they (1) had "repeatedly partnered" with New Jersey companies to develop pharmaceuticals, (2) had engaged a consultant in the state, (3) had used a New Jersey Transfer Agent, (4) had sourced materials and equipment from the state, (5) had paid more taxes in New Jersey than most, if not all, other states, (6) had entered into confidentiality agreements with entities in the state, and (7) had asserted counterclaims in the New Jersey Court in an unrelated matter. After jurisdictional discovery, the Court concluded that these contacts were not sufficient to establish general jurisdictional. IPC had in fact entered into drug development agreements in the past with New Jersey companies, but these were found to be inadequate to support jurisdiction. One of these agreements was with Elite Laboratories and Elite Pharmaceuticals to develop a generic Prevacid product. However, this agreement was in 2005, and no

drug development actually commenced. IPC also entered into three agreements with Par Pharmaceuticals, Inc. ("Par") to develop generic Focalin XR, generic Coreg CR, and a third undisclosed generic product. The work for these agreements, however, was performed primarily in Canada. The Judge did note that all of these agreements were unrelated to the present ANDA product, but such a fact should be irrelevant to general jurisdiction analysis.



As for the other factors, the Judge noted that IPC had made "relatively random purchases" from companies located in New Jersey, and that these were insufficient, alone and with other contacts, to confer general jurisdiction (quoting the Supreme Court's 1984 *Helicopteros* opinion ("mere purchases, even if occurring at regular intervals, are not enough to warrant a State's assertion of *in personam* jurisdiction over a nonresident corporation in a cause of action not related to those purchase transactions"). As for the tax payments, IPCI did pay \$26.95 to New Jersey in 2010 and \$10.13 in 2009. However, even though these amounts "dwarfed" the single penny IPCI paid in taxes in Wyoming in 2009, the Court found that Astra's tax argument was "a bit overstated." Finally, the confidentiality agreements were with regard to "potential" or "possible" business relationships, with no evidence that they were ever consummated, and the litigation in question in which counterclaims had been filed was controlled by Par, not IPC. When viewed in their totality, the Court found that these contacts were insufficient to establish the continuous and systematic contacts with New Jersey necessary to establish general jurisdiction.

To establish specific jurisdiction, it is necessary to focus on the relationship between the claims and contacts. Of course, in a Hatch-Waxman action, the technical act of infringement is the filing of an ANDA. Astra pointed to three activities related to IPC's ANDA filing that were allegedly "purposefully directed" at New Jersey. First, Astra alleged that IPC sourced its magnesium stearate for the ANDA product from a New Jersey company. The evidence was to the contrary, however, showing that the dealings were with a Missouri office, and that the magnesium stearate was produced in St. Louis. Second, Astra pointed out that the packaging for the ANDA product was obtained from a New Jersey company. Even if this were true, however, the claim of the litigation arose from the quetiapine tablets themselves, not the packaging. Finally, Astra claimed that IPC relied on a Drug Master File held by Hetero Labs Ltd., which itself used a New Jersey Company, Pharm Q, Inc., as its U.S. Regulatory agent. However, the DMF relied upon by IPC in its ANDA filing was from a company located in Massachusetts, not Herero Labs. The Court, therefore, found that this case had nothing to do with the state of New Jersey, and that therefore Astra could not establish specific jurisdiction.

This brings up the question as to where an NDA holder can bring a Hatch-Waxman action when the ANDA filer conducts most, if not all, of its activities outside the U.S. (other than the filing of the ANDA, of course). The present opinion had no need to opine on this issue. In fact, in this case, IPC and IPCI had already consented to personal jurisdiction in New York, and had sought in the alternative a transfer of the New Jersey action to New York. The reason that IPC and IPCI believed that they were continuously and systematically doing business in New York was because IPCI was listed on the NASDAQ exchange, executives from both companies regularly travelled to New York for business, both companies used numerous New York companies to handle their affairs, and the companies worked with Par in New York. The problem is that it is the ANDA filing that is the act of infringement, and such a filing seeks approval to market an ANDA product throughout the United States, including New Jersey. By dismissing the case, the New Jersey Court was essentially allowing IPC and IPCI to select its own

forum, thereby depriving Astra, the NDA holder, of one of the benefits of bringing suit. Nevertheless, IPC and IPCI's contacts with New Jersey were tenuous at best, and Astra could have selected a more appropriate forum in the first place.

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