

Cubist's lawsuit against Teva keeps potential buyers wary, sources say

By Paunie Samreth, Sasha Damouni, and Jacqueline Kwong in New York

- * Cubist has been marketed to various firms, but there is a takeout hesitancy
- * No comment on takeout from CEO; Cubist has viewed, to acquire, late stage products this year
- * Reissued patent gives Teva an argument of double patenting against Cubist
- * Double patenting argument surrounds fact that Cubist's reissued patent might cover "new matter"

Cubist Pharmaceuticals (NASDAQ:CBST), the Lexington, Massachusetts-based antibiotic company, could have problems selling itself in the near term due to litigation and patent woes, said industry sources.

On 9 February 2009, Teva (TLV:TEVA) submitted an abbreviated new drug application (ANDA) to the FDA seeking an approval of a generic version of Cubicin. Teva claimed that patents filed by Cubist are not infringed and/or invalid. Cubist responded by filing a patent infringement lawsuit against Teva.

Cubist does not comment on takeover rumors, said Michael Bonney, CEO. However, the company has viewed some interesting products in the biotech industry and could acquire late stage products this year, he said. He did not disclose further specifics, only to say that the company will approach acquisitions with discipline.

Cubist, with a market cap of USD 1bn, derives most of its revenues from Cubicin, an intravenous antibiotic with activity against methicillin-resistant *Staphylococcus aureus*, or MRSA. Cubicin revenues increased 68.8% to USD 422.1m in 2008.

An industry banker who claimed familiarity with Cubist's strategy said the company would be an attractive target for larger pharmaceuticals, but the strength of its intellectual property is often questioned. It has been rumored that Novartis (NYSE:NVS) has shown an interest. He acknowledged that Cubist could be considered a one product company and therefore would be digested easily in a deal.

A source close to the situation admitted that Cubist has been marketed to various companies, and "should have been acquired some time ago." The source said Cubist is attractive as it has a market position and infrastructure that could integrate easily into an acquirer's portfolio. However, he said there has been a lull in terms of interest, and even questioned why Cubist has been unable to get enough traction from buyers. He would not provide additional details.

Questions about the strength of its patents prior to Teva's ANDA have been raised by the company's investors, said the banker familiar. Until patent issues are resolved, the prospects of a sale of the company are at a standstill, he added.

"Its pipeline gap is considerable, with the next product four or five years away so it could make acquisitions, but ultimately, Cubist is considered a target," he added. The banker said he did not believe that Cubist would be able to find complementary acquisitions, as there is a scarcity of late

stage infection-based products.

Several attorneys were uncertain whether Cubist would win the lawsuit against Teva and even speculated that Teva's strongest argument would come from the fact that Cubist had to reissue one of its patents to correct the chemical structure of Cubicin.

Cubist's 5,912,226 patent, which covers the Cubicin compound, was submitted to be reissued in 2000. In 2006, the patent was reissued and labeled as patent 39,071.

Narinder Banait, a partner in the intellectual property group at Fenwick & West, said the Cubicin patent was reissued because the original patent covered the incorrect structure of Cubicin. Normally, such a mistake would not be a problem, but if the corrected structure changes the activity of the compound, then the court is unlikely to pardon this mistake, Banait explained.

A life sciences partner, who requested anonymity, agreed that Teva was likely to attack the fact that the patent was reissued because of the structural mistake. Double patenting, which is "judge-made law," states that a reissued patent cannot introduce new matter, he explained. Although Cubist merely corrected the structure of the compound, Teva is going to argue that this corrected structure is "new matter" because it has a different kind of activity or different toxicities than the original patented compound, said the partner.

Banait and the partner on background concurred that nine out of 10 of these chemically equivalent, but structurally different, compounds, exhibit dissimilar activity and toxicities. Most likely, this will strengthen Teva's claim of double patenting, said the life sciences partner.

Chad Landmon, a partner with the biomedical practice group of Axinn Veltrop & Harkrider, said the fact that Cubist's patent did not reissue until six years later, between the period of 2000-2006, suggests that there were problems with the reissued patent.

Apart from claiming double patenting, Teva can also attack the added claims to the reissued patent, Landmon noted. Potentially, Teva can argue that the additional claims were not sufficiently detailed or were not given sufficient enablement, he added.

Enablement is sufficient disclosure in a patent to allow a person, skilled within the trade, to carry out the invention. Enablement is required for patent protection.

Teva can also make a claim of non-infringement based on Cubist's method of use patents, said Warren Woessner, the founding shareholder of Schwegman Lundberg & Woessner. These method claims are typically considered weak and Teva can claim non-infringement by - for example - simply using a different dose for its generic Cubicin, Woessner noted.

Yet F. Dominic Cerrito, a partner with the life sciences group at Jones Day, noted that Teva would have difficulties defending itself in this lawsuit. The fact that Cubist's patent was eventually reissued indicates that the previous problems with the patent have now been resolved, he said. This plays in Cubist's favor, he added. In addition Cerrito disagreed that Teva would successfully claim that Cubist engaged in double-patenting. The argument that the different structure has different types of activity is only theoretical and could be tough to make, said Cerrito. Even if such arguments can be made, they would be dispelled by experts, he added.

Another attorney on background agreed that Teva would have difficulties defending itself. Having

a patent reissued indicates that the patent has gone through the patent prosecution process twice, and immediately, this patent has heightened power, said the source.

However, even Cerrito acknowledged that Teva's defense was not at a loss. Cerrito said in Cubist's patent, there is a lot of disclosure about prior art, which indicates that a claim of obviousness can be made, thereby invalidating the original patent.