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India IP Policies Unlikely To Change Until Local R&D Pipelines Mature – McKinsey

McKinsey singles out clinical trial policies as the top obstacle to Indian innovation, but also takes a closer look at IP issues that could be holding the country back.

CAMBRIDGE, Mass. – Although it cites clinical trial policies as the biggest obstacle to biopharma innovation in India, a recent position paper commissioned by the USA-India Chamber of Commerce (USAIC) also explores the adverse impact of India's IP policies, noting that little is likely to change in the next three to five years.

The 150-page report, authored by McKinsey & Co. and entitled "Will India Play A Meaningful Role In Global Biopharma Innovation?", was released during USAIC's annual biopharma and healthcare summit, held June 21 in Cambridge, Massachusetts. McKinsey's findings are based on an industry survey and more than 50 interviews with senior pharmaceutical executives, government officials and academics from the U.S. and India.

In a surprising conclusion, McKinsey found that intellectual property ranked only third – behind clinical trial policy and infrastructure, and research talent – as the biggest obstacle that faces India in driving R&D at scale. Yet the consultancy also acknowledged that Indian IP policies remain a concern, particularly among a "vocal minority" of U.S. pharma R&D heads (*"Sneak Preview: Clinical Trial Policies Top IP As Biggest Obstacle To Indian Innovation" — PharmAsia News, Jun. 19, 2013 4:53 PM GMT*).

In the report, McKinsey singles out several recent cases that have intensified focus on India's IP policies, including cases related to Pfizer Inc.'s Sutent (sunitinib), Bayer AG's Nexavar (sorafenib) and Roche's Valcyte (valganciclovir), Pegasys (peginterferon alfa-2a) and Tarceva (erlotinib) (*"War Of Words: Pfizer Battles With Top Indian Pharma Lobby On Key Policy Issues" — PharmAsia News, May 24, 2013 6:31 PM GMT*).

"The current flux on IP and patents policy is likely to continue and case-by-case discussions are expected," the report states.

Will Time Heal The Wounds?

Multinational companies have taken issue with several aspects of India law, particularly Section 3(d) of the India Patent Act, which bars patenting of incremental innovations that fail to demonstrate significant therapeutic benefits.

In a landmark decision, India's Supreme Court recently upheld Section 3(d) and denied patent protection for Novartis AG's blockbuster oncology therapy Glivec/Gleevec (imatinib). However, the court also made clear that Section 3(d) does not bar all incremental innovations from patent protection (*"India's Supreme Court Dismisses Novartis' Glivec Patent; Upholds Section 3(d) Of India Patent Act" — PharmAsia News, Apr. 1, 2013 4:54 PM GMT*).

For the innovative pharmaceutical industry, the best remedy for Section 3(d) may be time, according to McKinsey, which notes that Indian pharma companies are increasingly investing in their own R&D pipelines and will eventually want better patent protection.

The report highlights two recent approvals for new chemical entities (NCEs) – Zydus Cadila's Lipaglyn (saroglitazar) and Ranbaxy Laboratories Ltd.'s Synriam (arterolane/piperaquine) – and notes a rapidly increasing pipeline of NCEs in India.

Altogether, McKinsey counts 44 NCEs under development in India as of 2012, although the majority (23) are in Phase

I development or Phase II (18), with only three in Phase III. Still, as recently as 2005, India had only 10 NCEs in development, the report states, all in Phase I or II.

The relatively early stage of India's NCE pipeline means that policies are unlikely to change in the next three to five years, the report states. But over the longer term, as pipelines "materialize", policymakers could take a second look.

"Likely outcome could be a proposal for shorter protection for incremental innovation (three to five years compared to five in the U.S. and six to 10 in the European Union), with start in protection from time a new product is first registered in any country," McKinsey predicts.

Another lightning rod of controversy in the IP field is India's stance on compulsory licensing. Last year, in what was seen as a precedent-setting move, the Controller General of Patents granted Natco Pharma Ltd. India's first compulsory license to manufacture and sell copies of Bayer's kidney cancer drug Nexavar.

More recently, another local company has filed a compulsory license application for Bristol-Myers Squibb Co.'s cancer drug Sprycel (dasatinib), with industry watchers predicting that more applications are likely on the way (*"India's Decision To Uphold Natco's Compulsory License On Nexavar Holds Key Lessons For Innovators, Generic Makers" — PharmAsia News, Mar. 19, 2013 5:48 PM GMT*).

"Experts opine that CLs are not a trend in India," McKinsey says, "but will get discussed on a case-by-case basis." The consultancy advises innovator companies to "preempt the conditions of compulsory licensing by ensuring access, affordability and adequate 'working' of the patent in India."

But overall, McKinsey spends less than 10 pages out of 150 discussing IP issues. For a report on India's role in biopharma innovation, that might surprise many stakeholders given the recent war of words over patent rights between innovators and Indian generic companies.

Yet McKinsey sticks to its guns, saying it is a "myth" that IP is the biggest obstacle to India realizing its R&D potential.

"The bigger issue has been a lack of an ecosystem for clinical trials," the report states.

By Joshua Berlin