SCRIP
CITELINE COMMERCIAL

01 Mar 2024 | **News**

Lilly CEO: Affordable Generics And IP Support 'Not Incompatible Ideas'

by Anju Ghangurde

Lilly's CEO indicates that the long-standing IPR debate that has generally divided the developed and developing world is largely a "false narrative". The executive also called for lowering regulatory barriers in India amid expectations of the potential debut of Zepbound/Mounjaro in the country next year.

Tirzepatide may be on course to India but *Eli Lilly and Company*'s CEO, David Ricks, made clear that the enabling intellectual property rights (IPR) environment in the country leaves a lot to be desired.

The Lilly veteran referred to India's "special moment" in the world amid geopolitical tailwinds but stressed that the country will need to rethink certain historical positions in areas like IPR and also transform the regulatory environment to "join the globe as a leader in life sciences."

Addressing BioAsia 2024 in India, Ricks underscored that IPR was at the root of what the industry does "inventing new matter and improving its utility in diseases", without which the 12-15 year exercise costing $3-5bn per molecule would "never have been undertaken."

"I think it is time for India to reconsider its position on IP relative to our industry and enhance its controls providing a more consistent period of reward in-country and supporting those policies out of country," Lilly's CEO told a packed house at the conference in Hyderabad.

The absence of data exclusivity and restrictions on patent-eligible subject matter as covered in Section 3(d) of India's patent regulations have been among long-standing concerns for big pharma, though the Lilly veteran didn't specifically spell these out in his address.

Neither did he directly reference India's role, alongside South Africa in the World Trade Organization COVID-19 TRIPS (the Agreement on Trade-Related Aspects of Intellectual

Property Rights) waiver proposal, though The Economic Times reported Ricks as saying that India has lacked the interpretation of IP rules for the industry and has been a "proponent for loosening them globally." (Also see "*Pharma's Voluntary Licensing In India Successful In 2021 – But There Were Some Delicate Moments*" - Pink Sheet, 6 Jan, 2022.)

"Two Track System"

Ricks, however, minced no words on the long-standing debate around IPR that has more generally split the developed and developing world.

"That debate, I think, is largely a false narrative. We can have affordable generics that are broadly available for common diseases, we can make sure medicines are affordable for the developing world, and at the same time, support IP to create tomorrow's inventions, like our breakthrough Alzheimer's and obesity therapies that can serve the globe as it develops. These are not incompatible ideas," Ricks declared (*see side box).*

Lilly's CEO called upon India's policy makers to "embrace that idea" and collaborate with other developed nations to form a "two track system" that can support both types of products for medical need – "commonly used medicines that should be affordable for all and new medicines that can reach this population and others to really address the leading causes of adult diseases in the developing world."

IPR issues in India have long been a sticking point for foreign biopharma firms, though the government has moved to address certain concerns. Some heads of foreign firms have over the recent past, though, referred to progress in overall IPR

Tirzepatide On Course To India?

Eli Lilly's CEO, David Ricks, made references to the firm's obesity treatment that's "making us famous around the world" and also highlighted the huge burden of chronic conditions such as diabetes in India.

Obesity, he noted, is perhaps the primary cause of all adult diseases in the developed world, leading to over 200 chronic conditions, not the least of which has a major impact in India as well, such as Type 2 diabetes, hypertension and cardiovascular risk.

"We can now address the underlying cause of these diseases in a very significant way with scalable medical innovation," Ricks said.

India has an estimated 101m people living with diabetes, while 136m are pre-diabetic. Some physicians had previously estimated that about 67% of Type 2 diabetes patients in India have obesity, with the "thin- fat" Indian, which essentially refers to lower lean body mass but with higher subcutaneous fat, being a common phenomenon. The World Obesity Atlas 2023 has projected a "very high" annual increase in adult obesity in India at 5.2% from 2020–2035. Child obesity is projected to rise 9.1% during the same period.

enforcement in the country, while others maintained that the intensity of concerns around IP issues as a proportion of launch considerations have declined over the years. (Also see "*Astellas India MD On Action-Packed Run Ahead, Breaking The Glass Ceiling*" - Scrip, 27 Nov, 2023.) (Also see "*India Trials Scenario: Leaders From Novartis, IQVIA, PwC Signal Winds Of Change*" - Scrip, 22 May, 2023.) (Also see "*Foreign Firms Not Fatigued In India, Game For 'New Things'*" - Scrip, 28 Mar, 2022.)

India has, over the recent past, revamped its IP administration, proposed revisions to its IP rules and also brought down the average pendency for patent examination from 2,160 days in 2016 to 120 days in 2022.

Proposed amendments under India's Draft Patents (Amendment) Rules, 2023 include providing discretionary authority to India's Patent Controller to decide the maintainability of the representation of pre-grant patent opposition, and also a fee for such oppositions, while the time-line for submitting patent working statements [essentially commercial-scale utilization of the patented invention] has been proposed to be altered from yearly to once every three financial years.

These proposals, though, have drawn criticism as expected from civil society organizations and patient groups, who claim that the former could curtail their ability to file pre-grant oppositions to prevent the grant of "unmerited patents" on medicines to ensure timely availability of quality assured, affordable generic

These numbers certainly bode well for the potential debut of a new weight loss/diabetes treatment in India, with all eyes on pricing aspects and whether Lilly will opt for the established partnering route for products like tirzepatide.

The glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 receptor agonist was approved as Mounjaro for Type 2 diabetes in May 2022 and as Zepbound for obesity in November 2023. Some analysts have forecast peak annual sales for Zepbound of around $40bn in the mid-2030s – to put things in perspective that's more than half of Sri Lanka's 2022 gross domestic product in current prices. (Also see "*Lilly's Zepbound: The Biggest-Selling Drug In The World, Ever?*" - Scrip, 15 Nov, 2023.)

India has been part of global studies for tirzepatide, per data from the Clinical Trial Registry of India. Companies like *Cipla Limited* that already have partnering ties with Lilly have indicated their intent to present their credentials when opportunities open up for the product in India. (Also see "*Cipla Points To Large GLP-1 India Opportunity Amid Speculation On Lilly Deal*" - Scrip, 29 Jan, 2024.) The Economic Times reported that Lilly aims to launch the diabetes/weight loss therapy next year subject to regulatory approval and the supply situation.

Ricks also noted that India is expected to surpass China in the number of people diagnosed with diabetes and further explained

medicines.

Regulatory Regime

Back at the BioAsia conference, Lilly's CEO also underscored the need for regulatory reform, driving home the point with the strides made by China in the area.

While regulatory barriers may not be unique just to India, Ricks pointed out that over the last 20 years, there had been tremendous convergence between the European Medicines Agency, the US Food and Drug Administration and Japanese regulators and more recently, the Chinese regulators, which had led to "enormous efficiency" in developing medicines for the populations in those nations.

that obesity is a precondition disease to many metabolic conditions that afflict adults, diabetes included, along with hypertension, cardiovascular events and stroke. (Also see "*Biopharma's Winners And Losers Of 2023: Obesity Drugs Reshape Big Pharma*" - Scrip, 21 Dec, 2023.)

"These will become preventable with medicines like that my company makes and I think embracing that innovation will be critical to the success and longevity of India's economy and its people," he added.

"To the degree there are differences, it creates a less fair/transparent environment for Indian citizens to access global innovation. And it's actually a handicap on Indian companies to globalize their own innovations," Ricks explained.

Noting that harmonization is a multi-step process and "won't happen overnight", the executive acknowledged that the current system may have been invented for good reasons but a careful analysis of an unwinding may be helpful.

"I know that a global industry would support India further embracing the ICH [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use] rules, and beginning to lower these barriers, which don't add to the health of its citizens, but perhaps slow down new innovations arriving here in India."

Health Insurance Safety Net

Ricks also called for a wider heath insurance safety net in India, notwithstanding progress made by the government-financed program which provides over 514 million people some basic insurance coverage in the country.

Can Modicare Reshape India's Health Care Paradigm?

By Anju Ghangurde

27 Nov 2018

"But this is in-patient only. That's important. That's a basic first step. We would call to expand

that for common diseases like diabetes, where you can self-care at home, a more scalable low-cost model to reach so many in India," the CEO stated.

While this may seem a "difficult and expensive task", Lilly's CEO drew attention to another China success story and how the Asian giant scaled up coverage from roughly 15% of its population with some form of basic insurance in 2000 to almost 99% currently.

India's new government-funded health care program expects to expand access to treatment to more than 100 million families. Can it effectively deliver on its promise and also materially expand opportunities for hospitals and pharma?

Read the full article here

The Lilly long-timer, who has in the past led the US firm's China operations, noted that as the China economy grew, the government invested in the social safety net and built nationwide digital systems to implement that.

"It's been hugely successful. We can have our debates about how China does its business but as it relates to supporting basic healthcare, this is a giant success," Ricks asserted.

Lilly's CEO went on to draw parallels with India's banking system, which is now "legendary around the world", going directly to mobile devices and introducing "very low cost, low friction banking" for every citizen in this country.

"This is possible with health insurance. Such a move could really propel India to both have better health for its citizens, but also a vibrant life sciences economy, that would move it rapidly up the ranks of interesting places to invest for foreign investors, and domestic investors alike," Ricks maintained.