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Pre-Competitive Collaboration Would Help Pharmaceutical Productivity Crisis – If Lawyers Could Get Out Of The Way

CAMBRIDGE, Mass. – Greater R&D collaboration was the theme of the day at the star-studded U.S.-India Chamber of Commerce biopharma and healthcare summit.

But industry leaders ranging from Pfizer's Martin Mackay to Merck's Merv Turner to Sanofi-Aventis' Marc Cluzel agreed that building trust among big pharmaceutical companies, and with other stakeholders including academics and India service providers, is key to harnessing wider networks, improving pipeline attrition and bringing effective drugs to market faster and cheaper.

The format of the May 6 summit itself was perhaps the biggest indication that building trust and partnering – even with competitors - is now taken seriously in an industry known for fiercely defending its intellectual property rights.

Instead of keynote speakers rushing in for a presentation and rushing out again, leaders from the world of biopharma R&D, venture capital and India contract services remained at assigned tables in a hotel ballroom in a setting reminiscent more of an evening banquet than an all-day biologics conference. They listened to panels and keynotes, and engaged in a back-and-forth dialogue, often at the prodding of summit MC, and president of Pfizer Pharma Therapeutics R&D, Martin Mackay, who flashed a smile as he threatened to call on participants directly if they didn't request a microphone on their own.

Signs Of Progress

It is still early in the game, but a new world of collaboration is emerging, and Mackay highlighted two partnerships he believes are a sign of things to come. In one, Pfizer and GlaxoSmithKline have teamed up on a wholly owned subsidiary, ViiV Healthcare, focusing on HIV and AIDS, with each company contributing products and pipeline candidates ('The Pink Sheet' DAILY, Nov. 3, 2009). The move was widely seen as an effort to beef up the HIV focus of the two companies to compete with market leader Gilead Sciences.

But Mackay also mentioned another benefit, one he thinks dovetails with the trust and partnership theme of the summit. Although Pfizer controls only two seats on ViiV's board, compared to seven for GSK, one seat is occupied by Mackay, who noted that board meetings are held on GSK's campus, facilitating regular dialogue between Pfizer and GSK scientists.

"This is the way we should have been working for years," Mackay told scientists and executives attending the summit, hinting that additional collaboration between Pfizer and GSK could be in the offing. "And maybe if we had been, we wouldn't be in this productivity issue we have now."

In another example, Mackay mentioned a pre-competitive collaboration among Pfizer, Lilly and Merck to launch the Asia Cancer Research Center, which aims to collect and share pharmacogenomic data on Asia cancers, focusing on biomarkers for lung and gastric cancers (PharmAsia News, Feb. 24, 2010). Like with the GSK example, Mackay made the point that he had met recently with scientists at Lilly's Singapore Center for Drug Development, which under the partnership will manage more than 2,000 tissue samples in an open-source platform.

“This is one of the biggest changes in our industry, this willingness to work together in the pre-competitive space,” Mackay said. “Now the cynics could say this is purely out of desperation. And there is probably an element of that, because when we didn’t need to collaborate, we didn’t do it so much.”

But according to Mackay, the reasons for collaboration are not as important as what the joint endeavors mean for drug discovery. “These are really first-class collaborations,” he said. “I’m absolutely convinced this is the way we will dig our way out of the productivity challenges that we face.”

Don’t Compete Too Early

Indeed, pre-competitive collaborations were a major focus of discussion at the summit. J&J Global Head R&D-Pharma Paul Stoffels mentioned development of HIV biomarkers during the 1980s as another example where big pharma worked together to develop a framework that allowed for competition further up the R&D stream. Stoffels suggested that industry leaders sit down and hammer out how to better share and collaborate in the pre-competitive space.

McKinsey Asian & North American Life Sciences Co-leader Ajay Dhankhar suggested big pharma look to the airline industry as a model for collaboration, noting that alliance partnerships developed in the 80s were a success formula for a struggling industry, fostering the sharing of customer data among airlines while maintaining competition.

But there is a limit to how far collaboration can go, Stoffels noted. In the end, networks don’t discover drugs, people do. And pharma companies need teams of dedicated scientists who are likely to fail many times before getting it right, he said.

Nevertheless, pharma should work together to find targets or select likely responders, and save competition for later trials and R&D execution, suggested Rod MacKenzie, senior VP and head of worldwide research at Pfizer PharmaTherapeutics.

He highlighted a series of partnerships Pfizer has signed in Asia with academic institutions and contract research organizations and manufacturers, noting that most partnerships start small and expand over time as trust is built between the partners.

In one example, Pfizer in January expanded a partnership with Kolkata, India-based TCG Lifesciences: TCG will develop a portfolio of undisclosed molecules in several discovery target programs up to the nomination of preclinical candidates. Pfizer will own the compounds and provide research funding, and TCG is eligible for undisclosed research milestones (PharmAsia News, Jan. 6, 2010). The TCG relationship developed over several years, with the Indian company initially providing discovery chemistry work under a master services agreement, which Pfizer expanded in February 2009 to include integrated research services.

But MacKenzie also suggested that Pfizer needs to transform its one-to-one partnerships by linking them together into a “collaboration of collaborations.” Once accomplished, Pfizer should then link its network of partnerships to networks created by other big pharmas like Lilly and Merck, MacKenzie said.

That goal ought to be welcomed by other big pharmas. In a separate presentation, Sanofi Aventis Executive VP & Global Head of R&D Marc Cluzel summarized his partnership strategy in a PowerPoint slide that said: “Shared Strategy, Shared Networks, Shared Resources and Expertise, Shared Benefits.” Like Pfizer, Sanofi has been active recently in Asia, signing a deal with India’s Glenmark for transient receptor potential vanilloid (TRPV3) antagonist molecules, with the Mumbai-based pharma getting \$20 million up front and milestone payments that could bring in \$305 million more (PharmAsia News, May 3, 2010).

And like Pfizer, Sanofi also wants to turn its “preferred partners” into “preferred networks,” Cluzel said. The R&D chief is also on board for pre-competitive deals, telling attendees that big pharma could define the pre-competitive space in a contract, which would allow collaboration until research reaches a pre-defined point.

That would also sit well with Merck Chief Strategy Officer & Senior VP Emerging Markets R&D Merv Turner, who noted that many in big pharma now favor mechanisms for collaboration during early-stage research, including patent pools, provided IP rights are maintained further upstream for molecules that reach the market.

That's because the real skill in drug development – the playing field companies should compete on – is turning data into safe and effective medicines, Turner said. Indeed, according to Turner, what big pharma does best is reverse engineer. While the first molecule brought into clinic often fails, Merck and Pfizer are good at discovering what went wrong and making changes so that a drug eventually reaches market, Turner said.

And it's not just big pharma looking to partner. Also count in Vertex Executive VP Global R&D Peter Mueller, who pleaded for a commitment to openness in the preclinical space, particularly for research on neglected diseases like tuberculosis.

Neglected diseases are one area where some progress has been made, with GSK launching a patent pool last year for tropical diseases that is administered by BIO Ventures for Global Health ('The Pink Sheet,' Feb. 23, 2009). Alnylam also joined the pool, and last week South Africa's Technology Innovation Agency announced it would use the pool - containing more than 2,300 patents - to work on drugs for TB and malaria, partnering with local biotechs, including Johannesburg-based iThemba Pharmaceuticals, which joined the pool in January.

Blame The Lawyers?

So if everyone's on board, what's the holdup? Lawyers are responsible, of course, along with university technology transfer offices, according to the R&D heads.

Turner, half jokingly, said that more money is spent protecting early-stage IP than on early-stage research, and singled out tech transfer offices, in particular, as standing in the way of patent pooling.

Amgen Senior VP Research David Lacey was more direct, saying that pre-commercial collaboration and expansion of R&D networks falls in the cross hairs of IP lawyers, including big pharma attorneys, who look to protect everything they can as intellectual property.

It is already difficult for lawyers to sign off on one-to-one partnerships, said Lacey, who predicted that hashing out terms for a pre-commercial network could be a Herculean task.

"We basically have to decide that we don't like intellectual property lawyers to do this, because we would be so tangled up in language," Lacey said.

Yet hope remains. Pfizer's Mackenzie noted that R&D executives are eager to sign more deals like the pre-commercial collaboration involving Pfizer, Lilly and Merck on Asia cancers. Yes, attorneys have trouble signing off on such deals, Mackenzie acknowledged, but in the end the deal got done. And with big pharma desperate to speed up drug development and conserve resources, it's likely the R&D heads have the upper hand, at least for now.

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