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TRANSCRIPT

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Keynote Address

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FEATURING

Tonya L. Combs

Senior Vice President – General Patent Counsel, Eli Lilly and Company

CSIS EXPERTS

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Kirti Gupta: Welcome back from lunch, everyone. I think people are still making their way back, but in the meantime I want to close our lunch hour and invite Tonya Combs to come and give us her views from an inside perspective from a large company. So Tonya serves as the senior vice president and the general patent counsel at Eli Lilly. And she advises senior leaders at Eli Lilly and Company on IP strategy. She's leading a group of talented, experienced patent and trademark professionals at the company responsible for patent procurement, trademark procurement, maintenance, and litigation and enforcement for Lilly.

And Ms. Combs – or, may I call you Tonya? (Laughs.) Started her career at Lilly as a chemical engineer in research and development and optimizing the scale-up of clinical trial materials. She's held a number of positions in increasing responsibility at Lilly legal, focusing on patent prosecution, litigation, brand support, trade secret protection and enforcement, the GC for the oncology business units, and others. And before joining Lilly Research Labs in 2001, she received a B.S. in chemical engineering, and a J.D. from the IU McKinney – Indiana University McKinney School of Law in 2006. She also sits on the board of – IP board of directors and has served on the executive committee as a board liaison for IPO's Pharma Bio Issues Committee, and is active at the AIPLA.

Welcome, Tonya. Thank you for joining us. Love to hear from you.

(Applause.)

Tonya L. Combs: Thank you so much for that warm introduction. It may be longer than my remarks. (Laughter.) It's truly an honor to be here with you today to talk about such an important topic. As mentioned, I'm general patent counsel for Eli Lilly and Company, where for nearly 150 years our purpose has been dedicated to creating new medicines that make life better for people around the world. We've seen and heard this morning about some amazing advances in science that have brought greater understanding to the root causes of disease and accelerated the pace of biopharmaceutical innovation.

From RNA technology to the curative power of gene therapy, to GLP-1/GIP receptor agonists that treat obesity and potentially many more diseases, innovation has transformed the way we treat some of our greatest health challenges and has changed lives for the better. And to help further that, in 2023 alone Lily invested $9.3 billion in research and development dedicated towards finding solutions to treat disease.

Unfortunately, as the pace of innovation has accelerated, so too have the headwinds that work against it. As some in this room know very well,

bringing new medicines to patients often involves multiple failures over decades, and costs $2.6-2.8 billion in investment to discover, develop, and commercialize new medicines at a global scale. Financing the high risk, high failure, and years long endeavor of bringing new medicines to patients requires the incentives that robust intellectual property protection brings.

In addition to incentivizing innovation, effective protection facilitates collaboration and enables partnerships that advance a shared goal of improving patient lives. We heard some great examples of that this morning. Specifically, IP rights serve as a mechanism for facilitating collaborative discussion and research. They bring together parties whose shared experience and expertise can address a medical challenge possibly more effectively and possibly faster than either party alone. Importantly, fair and predictable IP protection also provides the legal certainty necessary for collaborators to freely share technology without comprising ability to continue to invest in future innovation.

Detractors of the pharmaceutical industry will argue that the current IP system favors innovators too much, delays generics and biosimilars, and leads to higher drug prices. As a result of this false premise, policymakers and governments around the world have implemented or are proposing policies that weaken IP protection in the name of affordability and patient access. For example, in the United States the Inflation Reduction Act essentially reduces the effective protection for small molecules. We're seeing the impact of that policy as biotech firms shift focus away from oncology research, where small molecule therapeutics play a particularly important role.

However, at Lilly we don't believe a tradeoff between innovation and affordability must be made. We believe America can and should aspire to a system that incentivizes both world-leading innovation and affordable costs for patients. As Hemal said this morning, predictable, fair, and robust patent protection is the foundation for delivering affordable medicine to patients. It improves patient access to new treatments over time by providing the pipeline for biosimilars and generics, a dynamic critical for sustainable healthcare systems in a resource-constrained world.

Because of the limited duration of patent protections, expiration of those facilitate the shift to generics and biosimilars, creating financial savings for patients and budgetary headroom for healthcare systems, allowing them to expand access to treatments including to new medicines. In fact, today 90 percent of all prescriptions are written for generics, which have reduced patients medical costs significantly – by some estimates, as much as 39 to 95 percent. When patent protection

ends, we welcome generics entering the market, but without the right IP policies in place, biopharmaceutical innovation simply isn't possible.

So when we think about IP policy reform we must ensure policies move toward a sustainable innovation ecosystem that does two things – both promotes a robust pipeline of innovative medicine and reliably drives entry of biosimilars and generics. Balancing these goals requires a reliable period of exclusivity for innovators, followed by reliable and well-utilized approval pathways for generics and biosimilars once that protection ends. The Biologics Price Competition and Innovation Act, or BPCIA, and Hatch-Waxman are examples of critical frameworks that strive to achieve this balance, in addition to fostering transparency and predictability.

Factual misrepresentations in the rare but often cited instances of gamesmanship threaten to undermine these frameworks' intent and enduring success. As an example, Lilly's most commonly used insulin, Humalog, has been off-patent for more than a decade. Yet we hear often the erroneous claim that Lilly has abused or extended patent protections to keep biosimilars off the market. We welcome follow-ons, so that as an innovator we can focus on developing new medicines. And with appropriate IP incentives, this is how biopharmaceutical innovation ecosystems should work.

As a call to action, IP reforms generally should, first, ensure predictable, reliable, and robust exclusivity periods for innovators, and then predictable, reliable, and well-utilized approval pathways for generics and biosimilars, including efficient pathways towards determining biosimilar interchangeability. They should also ensure high-quality patents get granted, which is to the benefit of all of us, and prevent practices that give innovators a bad name, like the rare misuse of listings in the Orange Book in a way that could potentially delay generic entry.

And finally, they should establish the U.S. as a global leader and example for other nations in ensuring the innovation ecosystem continues to fuel future medical breakthroughs. Lilly joins a group of its peer companies in supporting patient-focused IP reforms that promote scientific and technological progress for people, health systems, and society. Providing affordable healthcare and addressing unmet patient need are societal – society – social, that's the word – social imperatives. And strong IP systems are essential to achieving both. Thank you for your kind attention today. (Applause.)

Dr. Gupta: Thank you so much, Tonya.

(END.)