

Under Secretary of Commerce & Director of the USPTO David Kappos

June 29, 2011

Biological Industry Organization – Celebrating 30 years of Biotech

“From *Chakrabarty* to Today”

*Draft remarks as prepared for delivery*

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- Good morning everybody and on behalf of the United States Patent and Trademark Office, I want to thank you for taking the time to join us in a conversation about an industry that has evolved leaps and bounds since it’s inception—biotechnology.
- Often we regard necessity as the mother of invention, but in a world constantly reshaped by novel & disruptive technologies, it is often **curiosity**—a willingness to push new boundaries and the courage to challenge traditional thinking—that can unlock new ideas, new truths, and new industries.
- Through human ingenuity, research, and **that very desire to explore** Dr. Ananda Chakrabarty unlocked a new world of possibilities through the notable *Psuedomonas*—a genetically engineered bacterium that had the ability to break down crude oil and clean up toxic spills.
- Bacterial manipulation represented a huge leap in our ability to combat grave environmental disasters by catalyzing a reaction that broke down

the toxins into simpler substances, readily eaten by aquatic life. But as we all know, the significance of his research didn't stop there.

- By producing a bacterium with markedly different characteristics from any found in nature, and especially one boasting such significant utility, the highest court in our land declared the living bacterium patent-eligible.
- Not only did this establish a sweeping precedent for future biotechnological discoveries, but it unleashed the opportunity to leverage the life sciences into new industries, new jobs, and new solutions.
- By allowing bio-patents to fuel the fire of our creative genius in addressing *our most human of* problems—advancements in medical therapies started granting families a new lease on life. Crop modification allowed more farmers to grow & more families to be fed. And manufacturing more efficient energy molecules set us on the path to sustaining a greener renewable-fuels-economy.
- There is no question that the *Chakrabarty* pivotal decision had a seismic effect on US patent policy, giving birth to a new mode of thinking at the United States Patent and Trademark Office.

- And while we gather here in the light of this case’s 30<sup>th</sup> Anniversary and reflect on its history to infer guidance for the road ahead—
  - **Today, we also stand at the precipice of a new history.**
  - One that, through Congressional patent reform legislation, will historically redefine the nexus of patenting and innovation.
- Just last week the U.S. House of Representatives demonstrated significant leadership in passing the *American Invents Act*—representing a major step towards transforming our patent laws to account for the modern stresses and expectations of a fast-moving 21<sup>st</sup> century global economy.
- While we are diligently working to reconcile the bill with a version passed earlier this Spring in the Senate—we are stand at the threshold of major change and a truly “Jeffersonian moment.”
- Innovation is at the heart of human progress and patents are how we drive that progress forward, so by working to reengineer the process of securing IP rights from the ground-up, patent reform will allow small and independent inventors to move their ideas to the market place faster and enable all of you to do your jobs more easily.
- By doing away with multiple sets of disjointed IP regulations, that are all to often gamed and exploited, we can streamline processes that

optimize patent quality and minimize barriers to research, development and growth.

- And if we get this right, we can foresee resolutions to post-grant review processes that take shape in less than one year.
- If we get this right, we can equip our agency with the thousands of additional examiners it will require to tackle the backlog—which for far too long as been an enemy of progress.
- If we get this right, we can confirm the strength of patents efficiently or even promptly let businesses know that their claims are in fact not strong enough.
- Either way, efficient processing grants independent inventors and large biotech firms alike the assurances you need to move *your* technologies and services forward. That way, **if we get this right, business can conduct business...without constant speculation or endless arbitration.**

[PAUSE]

- Let me be clear—should patent reform be signed into law, implementing a robust IP infrastructure around it will not be easy—**but we are up for the challenge.**

- Through judicious rule-making, and proactively advancing thoughtful interpretations of the new laws in the courts, we will proactively be able to actualize American innovation, and not just leave them idling in the pipelines as jobs that could have been.
- And this is particularly critical because the growth-potential, vitality and economic leadership of the United States has been, and continues to be, deeply rooted in American innovation.
- Since we live in a world where information and commerce increasingly reach far beyond any of our borders, and innovators are constantly seeking to tap markets abroad—**it is imperative that we also lead the charge in articulating the need for building a collective IP system** that offers consistent, cost-effective ways to obtain reliable patent rights in multiple jurisdictions.
- So patent reform is not solely about the United States’ interest, it is part of a larger assertion of American leadership.
- By signaling to our constituencies around the world that we are serious about coordinating our patent policies and serious about collaborating with other offices in devising real solutions that will cut down on workflow redundancies, the United States can lead the charge in reigniting substantive *harmonization* discussions.

- By meeting with Asian countries in March (APPC), engaging our European partners over the last three months (Brussels, London), following up with the world's largest patent offices last week in Tokyo, and securing the First Inventor to File transition in our patent reform bill—the USPTO has demonstrated a strong desire to ensure that the 21<sup>st</sup> century IP dialogue is a global one.
- That unilateral charge, inspired by a global ethic, is permeating in a way that's changing the dialogue, tenor, atmosphere and prospects of stakeholders engaged in all IP norm setting processes.
- It was reflected in our ability to engineer a change in tone around copyright discussions negotiated in Geneva last week, and it was reflected in our ability to gain widespread support for global Harmonization dialogues at the APPC conference in Washington last Spring. All of which indicates that **US IP leadership in the Obama Administration is not only about retooling the way we innovate at home, but also recalibrating our ability to lead through innovation abroad.**

[PAUSE]

- So whether we are reflecting on the past and considering the impact of patenting elemental molecules, or reflecting on the future of a truly Jeffersonian moment for our patent system—all of us will continue to face challenges in navigating the IP terrain.
- There will be challenges galore—and as many of you in the biotech community are all too aware, there will be a also be a fair share of controversial cases. But whether we’re debating *Prometheus* or *Myriad*, conversations like those hosted by the Biological Industry Organization this week help us showcase technologies and examine both historic and developing elements in intellectual property.
- Inspired by a fundamental truth that **IP is the premiere global currency for creating value from innovation**, conferences and dialogues like these allow us to determine how we can best cultivate technologies for the next 30 years, so we give ideas the vehicles they need to spread across continents and societies...inspiring tomorrow’s Chakrabartys for generations to come.
- Thank you and I look forward to a productive dialogue.

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