INNOVATION COUNCIL

Summary of TRIPS Council Special Session Presentation
Jennifer Brant, Innovation Council
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At the TRIPS Council Special Session in September 2023, **Jennifer Brant** presented recent interview-based research projects, the findings of which were published in reports entitled *Unprecedented* (2021, co-authored with Prof. Mark Schultz), *Making Biologics* (2022), and *Biomanufacturing Resilience* (2023). She noted that the topic of the Special Session – extension of the 2022 TRIPS decision – is really about ensuring adequate health products supply and extending biomanufacturing capacity, for health security. The three reports touch on these issues.

As documented in ***Unprecedented***, IP played an enabling role at all stages of the COVID innovation response:

Development of relevant background IP. Existing technologies and know-how were quickly leveraged for the pandemic response. These were the result of past R&D, enabled by IP within the biopharma innovation ecosystem. In some cases, public research outcomes were moving to market via hand-off to companies. COVID technologies were "overnight successes years in the making".

Development of COVID technologies. Collaboration was crucial to developing and repurposing COVID technologies in record time, and for developing and optimizing the manufacturing processes for them. Nobody could develop and deliver products at the scale needed on their own. IP made it less risky to work with others.

Scaling manufacturing for a pandemic response. Collaboration was essential to establish the necessary global manufacturing networks; in-house capacity was inadequate for a pandemic response. Capable partners were identified (not an easy task) then innovators shared technology and know-how with them, also helping them to set up supply chains and clear regulatory hurdles.

Investments for the pandemic response. IP enabled investments in a highly uncertain environment. Companies produced at risk, redirected resources to COVID, made commitments to suppliers, set up voluntary licensing arrangements, and upgraded manufacturing capacity – even before receiving regulatory approval. Government action helped to de-risk such activities.

Industry leaders interviewed for *Unprecedented* said that, had there not been IP protection, their companies would have supported the pandemic response but with less collaboration; sharing tech and know-how would have been unduly risky. This would have resulted in a slower, and perhaps very different, pandemic response. Without collaboration, manufacturing at the scale needed to fight COVID-19 would not have been possible.

By mid-2021 there were already 300 vaccine partnerships (more than 230 involving tech transfer). Technology and know-how *were* shared during the pandemic response. IP was managed to maximize global supply.

Making Biologics and ***Biomanufacturing Resilience***, focus on promising practices for building resilient biomanufacturing capacity globally.

Making Biologics identifies four key pathways for building capacity, based on historic evidence and insights from biologics industry leaders. All the pathways require collaboration and tech transfer, along with legally certain business environments that include IP protection. One approach for building vaccine production capacity is "backwards integration"; companies start with activities like fill and finish, then work side-by-side with tech transfer partners over many years to gain expertise and move up the value chain, ultimately performing R&D and activities like bulk antigen production. A backwards integration success story is Biovac (South Africa).

Biomanufacturing Resilience suggests actions for governments and companies to reinforce biopharma supply chains and thus improve healthcare delivery and pandemic preparedness. The report highlights the significant, IP-driven innovation in the upstream part of these value chains, where companies deliver manufacturing equipment, consumables, and services like facility design and workforce training. Such innovation is facilitating the establishment of efficient, flexible biopharma production in more regions. Upstream companies are often global tech transfer partners for regional manufacturers, with IP facilitating technology and knowledge exchange. The report suggests that governments contribute to resilience by tackling trade barriers, improving regulatory systems and regulatory coordination, and providing financial and other support for local producers. It cites the range of factors – including workforce, procurement and demand, and access to raw materials – that influence success when extending biomanufacturing capacity.

Conclusions:

- IP played an important enabling role in the COVID response and would undoubtedly support rapid pandemic innovation in the future as well.
- IP continues to facilitate tech transfer and other collaborations that build global biomanufacturing capacity across regions, contributing to health security.
- Work at the WTO is needed to ensure trade policies align with public health goals; for example, export restraints were problematic during the pandemic and their use should be disciplined.

Jennifer spoke in her personal capacity.