INNOVATION COUNCIL

AI and the Bio-Pharmaceutical Sector

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The World Intellectual Property Organization (WIPO) recently hosted discussions about the relationship between artificial intelligence (AI) and intellectual property (IP). Mr. Corey Salsberg, a globally recognized attorney in the fields of IP and innovation law and policy, and Vice President and Global Head of IP Affairs for Novartis, was invited to take part in the second panel featuring Stories from Innovators – A Real Life Business View on AI Innovation. This note is based on his remarks, which provide examples from Novartis' R&D and other activities to illustrate how AI can be applied to enhance bio-pharma innovation, along with the related IP implications.

Discussions about AI must be grounded in the real-world context and environment where such tools are being used. WIPO's organization of expert dialogues about AI and IP is welcome since, too often, these issues are talked about in the abstract.

In relation to the innovative bio-pharmaceuticals industry, conversations about AI and policymaking should begin by considering the broader context of the major forces that are shaping the future of the industry, both in terms of the opportunities they present and the challenges they pose. Below are four examples of them.

First, scientific knowledge about the basis for disease has expanded at a rapid pace. One example is in the field of genomics. This field aims at understanding the genome. Scientists now have a good appreciation for the root causes of many different diseases, the personalized nature of many diseases, and therefore, new pathways toward personalized cures and treatments like gene therapy.

Second, along with these revolutions in science and the ability to use digital tools to collect real-world patient data, researchers are facing massive amounts of new information. There is a need for the capacity to analyze that information so it can be put to use for the advancement of technology and medicine, and the good of humanity. One example of the scope of information confronting scientists relates to DNA, which has about 3.2 billion base pairs of information or 20'000 genes. We need solutions to analyze massive amounts of data in order to make use of them for positive applications.

Third, economics is a key factor shaping the bio-pharmaceutical industry. The costs of research and development have been steadily rising over the last several decades. At the same time, healthcare budgets have been increasingly strained, and this is likely to continue during the phase of economic recovery after the pandemic. This means that bio-pharma innovators must be able to show the value that new medicines bring to society, to individual patients, and to healthcare systems. Value can be understood as improving patient outcomes and/or lowering

the costs against the status quo. Companies are seeking new ways to make R&D more efficient and to maximize the use of data to ensure that treatments are as effective and as tailored as possible to the individual context.

Fourth, as is the case with many healthcare industries, there is the classic pressure of survival. Bio-pharma innovators leverage the latest technologies to stay ahead of other bio-pharma companies. Also, the changing dynamics of competition in the healthcare space, in part due to the rising use of AI solutions, means that bio-pharma companies are contending with new entrants to the field. These include companies like Google, Amazon, and Apple, along with healthcare tech startups.

To further set the stage for analyzing AI and IP in the bio-pharmaceutical sector, it's important to start with the baseline, that is, the basic blueprint for pharmaceutical R&D, and the key factors that shape innovation in this sector every day. The process of bringing a new treatment to market is one of inherent complexity, time, failure, and costs. Companies analyze roughly 10'000 chemical compounds, on average, to get to one successful drug candidate that is approved as safe and effective. Even once clinical trials begin, with retesting on animals and then on human beings, there is only a 12 percent success rate. Of the candidates that looked promising and that were put into clinical trials, 88 percent of those will fail. It takes about 10 to 15 years to complete this entire process and, at the end of the day, it costs billions of dollars to get a drug to market. This is in large part because there are so many failures when working to get something over the finish line.

This may sound negative but there is also a positive message here about the opportunity for AI to improve every aspect of the above process.

AI can be used to enhance early drug discovery. Novartis has over one billion effective drug candidates in its compound libraries. This is a significant number of compounds to test if researchers have to start from scratch every time they want to find something that might be relevant to a target of interest. AI is starting to revolutionize the way that companies can approach this challenge. Today, AI and machine-learning driven software similar to facial detection technology is being employed to teach a computer to find compounds relevant to a target. AI solutions can search for compounds with similar characteristics or with chemical structures that have a known ability to bind to a target of interest. This is just one way of applying that kind of technology.

AI is not only being used to accelerate the identification of connections that are already known. It can also be used to look at a set of images, on a massive scale, and make its own connections. These are connections that a researcher may not have been able to make before due to the vast size of the data sets. AI is also now being used in what is called generative chemistry, which involves software using the connections that it finds to profile and propose its own virtual molecules as drug candidates, which human scientists can then pick up and

further develop, test, and refine. Using approaches like this, some experts predict that fully designed therapeutic proteins could be built by AI by the year 2030.

AI is also relevant to clinical trials, which are in the middle of the drug development process. AI-assisted and digital tools are already helping to make clinical trials more efficient than they have been in the past. Novartis has developed a platform, called NerveLive, that uses an assortment of different AI-assisted tools to monitor the thousands of clinical trials that are going on around the world at any given time. This helps the company to identify and fix inefficiencies or other problems at any given site. It is like an air traffic control system for clinical trials, providing a high-level view and enabling experts to identify where the issues are, to make trials more efficient.

In addition, a host of digital and AI-assisted tools are being used to take clinical trials out of the hospital and into people's homes. This not only helps to expand patient pools. It can also help to reduce costs and increase efficiency. Eventually, AI may be able to help eliminate at least some forms of clinical trials.

Novartis alone also has around two million patient-years of anonymized data in databases from decades of past clinical trials. The company has been running a project, "Data 42", that converts all of this data from past clinical trials into a common format to create a database that can be mined to find new correlations between drugs and diseases. Creating this database is a massive challenge. As an example, imagine looking across years of historic clinical data to assess whether a factor like gender might impact a certain clinical response or an outcome. To do that kind of analysis using AI requires, first of all, determining the gender of the patient from that data. This may sound simple to do, but the reality is that some past clinical trials referred to gender with male or female, others used just the abbreviation M or F, and others used the terms masculine and feminine. Therefore, data needs to be standardized into one common form so that AI tools can be applied to sort through and start making the kinds of connections needed to develop new drugs.

AI also has important uses after drug approval, from diagnosing and imaging diseases to better understanding treatment efficacy and improving patient compliance. As one example, Microsoft and Novartis teamed up to develop a program called "AI4Leprosy". This is one of the oldest diseases known to humanity. Although today this is a curable disease, thanks to modern medicine, 200'000 people are still diagnosed with leprosy every year. It is a disease for which earlier diagnosis means a better clinical outcome. This can be done using tools like AI4Leprosy, which has been trained using anonymous images of leprosy from Brazil and India. (The reason for using images from these countries is simply that they have the highest burden of the disease.) This program has created the potential to significantly accelerate the early diagnosis of leprosy through creation of an algorithm that can be put on a phone, to support remote diagnosis without the patient even coming into the clinic.

Once a treatment is on the market, AI tools can also improve patient outcomes. For instance, one post-launch AI application, "AI Nurse", provides an AI-enabled digital platform for managing heart failure in China. This is a partnership between Novartis and Tencent. There are roughly thirteen and a half million patients in China with heart failure and, for many of them, there is no established primary care structure. As a result, adherence to prescriptions once the patients leave the hospital can be poor. AI Nurse uses a collection of AI-driven tools to manage heart failure from home, to improve compliance and therefore prognosis. It does things like monitoring daily health indicators, predicting disease progression, and even setting up follow-up appointments and making sure the prescriptions are renewed. The partnership has recently been using WeChat, which is a social platform in China, to help integrate this AI tool into everyday life for Chinese patients.

The future of AI in the bio-pharma sector is extremely promising and exciting. But realizing the potential of AI application in the sector will require the right policies, including in the area of IP. First, IP protection will be needed to incentivize R&D for the continued development and commercialization of AI-driven solutions. Second, the growing use of AI to enhance and accelerate R&D in fields like bio-pharma means that many downstream inventions will rely at least in part on AI. IP policies should ensure those downstream inventions can be protected and managed using IP rights, so they can be not only created in the first place, but also published and ultimately commercialized.

The inventorship question linked to downstream inventions that are made either by AI or with the assistance of AI is a near-term challenge for policymakers. IP systems in different jurisdictions are being tested in this regard, leading patent authorities in the US, Europe, the UK, and Australia to hold that because AI cannot be an inventor, no patent can be issued in cases where AI developed the invention. As AI contributes more to R&D, and humans are doing different roles, if not relatively less, the question as to where to draw the line will need resolution. Undoubtedly, WIPO will play an important convening role for stakeholders to discuss such matters.

The above is based on Mr. Salsberg's presentation at the WIPO AI and IP Dialogues. Click here to see the WIPO recording (2:53).