Dr. Francis Gurry
Director General
World Intellectual Property Organization
34, Chemin des Colombettes
1211 Geneva 20
Switzerland

February 14, 2020

Dear Dr. Gurry,

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) represents the world's leading research-based biopharmaceutical companies and associations. Our members, and the millions of people they employ worldwide, are dedicated to inventing, developing, and delivering valuable medicines and vaccines that enable people to live longer, healthier, and more productive lives.

IFPMA appreciates this opportunity to provide inputs on the document WIPO/IP/AI/2/GE/20/1 Draft Issues Paper on Intellectual Property Policy and Artificial Intelligence, ("Draft Paper"). As an official observer to the World Intellectual Property Organization (WIPO), we applaud its commitment to promoting the legal certainty of intellectual property rights related to inventions on, and which arise from using Artificial Intelligence (AI). The Draft Paper correctly highlights that AI affects nearly all research-based industries and has widespread applications throughout economies and society. The Draft Paper also correctly observes that, as a new and rapidly developing field of technology, AI raises questions related to IP and legal systems generally, which are currently being discussed by governments and other stakeholders around the world.

It is our belief that that these discussions, and the interest they have generated, are important, but must be undertaken in a measured manner, in the proper context, and with input from all interested stakeholders. Ultimately, they provide an opportunity to reflect on the success of the IP system in incentivizing innovation and disseminating technology over the last couple of centuries. These discussions also serve as an important reminder that, while new technologies will raise questions about the applicability of IP rights – similar to what has occurred in respect of prior technological developments (e.g., computer-implemented inventions), the system itself and its core principles remain fit for purpose.

For many IFPMA member companies, AI is already a technology being used in research and development (R&D) of innovative medicines. For example, AI technologies have been used to assist some IFPMA members to develop novel approaches to cancer treatments by simulating physiological and biochemical processes, such as immune system responses. AI computational modelling plays an important role in facilitating personalized cancer therapies by enabling the decoding of bioinformation (*e.g.* DNA and/or other clinical information).

Similarly, through the use of AI technologies such as machine learning, some IFPMA members are able to monitor clinical trials in real time as they are conducted around the world. These innovative clinical trial designs and systems help reduce costs and accelerate product approvals. Further, using digital tools such as mobile software applications in combination with data analysed by AI, some IFPMA members are able to diagnose patients earlier and analyse progression of diseases with more granularity than can be accomplished via more sporadic doctor-patient visits.

The investment in, and use of, AI in the biopharmaceutical field can be expected to continue to increase, and will help improve patients' lives by finding new and innovative medicines, vaccines and treatments more efficiently than currently.

We hope that in submitting these comments below we might assist WIPO and its members to better understand IP-related issues raised by AI that impact our industry.

Biopharmaceutical Innovation, AI Technologies, and Intellectual Property

IFPMA members make tremendous human and capital investments to research, develop and make available medicines, vaccines and other therapies to patients around the world. Intellectual property protections, including patents, provide the right incentives that drive and sustain those substantial investments in crucial prevention, treatments and cures, and the dissemination of these products to the patients who need them. Importantly, patents also promote the sharing of knowledge through the disclosure requirements of the patent system. WIPO and its members should continue to support IP laws which further incentivise innovation, including innovation made through the use of AI.

AI technologies and biopharmaceutical innovation have the potential to transform healthcare and patient outcomes worldwide. It is useful to note here that "AI" is an umbrella term covering a wide range of computing technologies, including as a subset the area of machine learning, which in turn includes the areas of artificial neural networks and deep learning. The implications for AI innovation of existing IP

frameworks can vary between the different areas of AI, noting that some computing approaches within AI have been dealt with by the IP frameworks for many years. It might be useful for WIPO to consider that the term "AI" includes different branches.

Patents

IFPMA urges WIPO and its members to take a pragmatic and measured approach in discussing IP and AI during the Second Session of the WIPO Conversation on Intellectual Property and Artificial Intelligence, to be held in May 2020. We believe that the Draft Paper poses the right questions for a meaningful debate regarding patents and AI technologies.

IFPMA supports internationally recognized and long-standing patent and non-discrimination principles, including the fundamental obligations underpinning the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement requires WTO members to make patents "available for *any inventions*, whether products or processes, in all fields of technology, provided that they are *new*, involve an *inventive step* and are capable of *industrial application*." TRIPS also requires that patents "disclose the invention in a manner sufficiently clear and complete for the invention."

Data protection

Biopharmaceutical innovation has already delivered revolutionary treatments and cures, increasingly with the assistance of AI. AI could be a powerful tool in helping to analyse vast amounts of data to further advance innovation in the biopharmaceutical industry.

The Draft Paper correctly recognises that the "classical IP system" affords certain protection to this type of data. As countries continue to consider the role that IP plays and, should in the future play with respect to data, IFPMA urges them to consider the many different types and sources of data that exist in today's complex technological environment. For example, while readily available data from public sources may not need or benefit from a system of incentives, other types of data that must be generated through investment and great effort would not exist without incentive systems. Any new *sui generis* right for data will need to carefully weigh its potential impact of this on innovation.

IFPMA thanks WIPO for requesting stakeholder input and leading the initiative to explore important questions relating to AI, innovation, and IP. Legally certain and

predictable IP protection, including patents, is fundamental to advancing AI and biopharmaceutical innovation. We welcome the opportunity to continue to engage in future dialogues and are happy to provide any additional information.

Respectfully yours,

Ms. Komal Kalha
Head of Intellectual Property and Trade Policy
International Federation of Pharmaceutical Manufacturers & Associations