INTELLECTUAL PROPERTY RIGHTS NEWS

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Dr. Acharya's Message



Dear Readers,

It is monsoon time and we hope the country gets sufficient rainfall. Rains have a bearing not only on the agricultural produce but have a cascading effect on the economy as a whole. Somewhere down the line in the process of this cascading effect, growth in IP registrations also depends, indirectly though, on a good monsoon.

One of the most important news in the last few months is about an Indian startup being granted patent for digital vaccine. "Digital Vaccine", the very word sounds new and on the face of it appears very innovative. It is an innovative concept and the same has been explained in detail in this issue.

There is a growing pressure on the US administration to curtail monopoly patent rights on the drugs it helps to develop. This issue explores the possibility of US President Joe Biden, daring to use march-in rights which is perceived as the new front against Big Pharma without upsetting the drug giants

As always, we welcome comments and suggestions from our esteemed readers.

Dr. Rajeshkumar Acharya

Proprietor

H K Acharya & Company

Indian gets Patent for Digital Vaccine

The US Patent office has granted the first patent globally to Bhargav Sri Prakash, an Indian Biomedical tech entrepreneur for a digital vaccine, a platform that prevents real world health issues through the metaverse.

FriendsLearn, a lifesciences startup, founded by Sri Prakash received the patent for the systems and methods for the digital vaccine which he developed as part of Carnegie Mellon University's digital vaccine project.

Digital vaccines use applications via smart-phones, tablets and other similar devices for nudging positive human behavior through neurocognitive training. This involves use of Artificial Intelligence and a gamified metaverse platform.

Sri Prakash who shuttles between his hometown Chennai and Palo Alto in California says, Digital vaccine can potentially prevent a wide spectrum of diseases ranging from Covid 19 and influenza to diabetes, cardiovascular disease, hypertension and certain cancers and even cognitive diseases.

To conduct clinical trials on children between the age of three and eighteen, Sri Prakash's Mobile game fooya, developed using the patented technology. In this game, the child is a super hero fighting junk food that an evil scientist is developing. Studies indicate that children who played the game fooya for just twenty minutes in a week, made significantly healthier food choices immediately and successive weekly sessions reproduced positive health outcomes.

Bhargav Sai Prakash is of the opinion that a vast potential exists in the



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form of an opportunity to safely and effectively prevent disease by non invasively stimulating the body and the immune system and bio markers through software.

Bhargav's patent applications which are still pending in India, China, Europe, Canada, New Zealand and Australia had applied for patent in the US about five years ago. Digital vaccines are currently being deployed in selected school partners of Carnegie Mellon's project across the world.

According to Rahul Ladhania, data science researcher and faculty member at the University of Michigan school of public health says that what sets digital vaccine apart from the analog and digital games is the digital vaccine's implicit learning and neurocognitive training mechanism components which can induce biomarker level changes in individual thus helping trigger lifestyle habit formation and reduce risk and incidence of diseases.

Ladhania says that while most of the interventions with the technology have so far focused on children, this can easily be adapted and extended to applications for preventing or treating a wide range of pathologies – like post traumatic stress disorder, mental health, sexual health – and for diverse target populations

Will Biden dare to use march-in rights?

Health advocates are asking Washington to use laws that allow patent override on drugs developed with public funds.

The public campaign against patent policies in the

United States is important for the rest of the world. It is the Washington model that has set global standards for the stifling monopoly rights enjoyed by innovator drug companies.

So when a group of leading public organisations recently asked the US Secretary of Health and Human Services Xavier Becerra to use his executive power to override patent rights on six important therapies, it signals the growing pressure on the US administration to curtail monopoly patent rights on the drugs it helps to develop — either through research collaboration with the National Institutes of Health (NIH) or public funding. Such a measure would widen access to life-saving medicines and reduce their prices.

The COVID-19 pandemic has prompted health activists to pursue such a strategy, spurred by the dispute between NIH and Moderna Inc over patent rights to the biotech company's mRNA COVID-19 vaccine. Moderna's vaccine was developed in collaboration with scientists of NIH who had earlier done the vital groundwork on mRNA technology, the reason why the vaccine could be developed in a short time.

Yet, Moderna excluded key NIH scientists when it filed patent claims on the vaccine allowing it to rake in huge profits. Who really owns the intellectual property rights (IPRs) on the vaccine is a vital question in these pandemic times. If NIH insists on its innovator rights that means the public organisation can license the technology to companies of its



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choice, in addition to receiving a share of the \$18 billion profits that Moderna is forecast to earn this year.

NIH scientists involved in the development of the vaccine are understandably incensed by Moderna's heist. The head of NIH has indicated that the dispute is headed for the courts. However, the US administration is holding back because of the clout of the pharma industry.

The Biden administration's response to the consumer and health organisations' demand that it use its march-in powers to curb monopoly rights will have a significant impact on how the world deals with the pandemic.

On the global front is the demand that the World Trade Organization (WTO) suspend its malign Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), proposed by India and South Africa in October 2020 and backed by over 100 developing member-states. It has made little headway because of the opposition of the EU and several other rich nations such as Japan and Switzerland.

The US is ostensibly in favour of the TRIPS waiver, but in a restricted manner and with several caveats. But it was clear from the start that President Joe Biden was unlikely to upset drug giants who are making extraordinary profits from the pandemic. Big Pharma, including vaccine-makers like Pfizer Inc and firms such as Gilead Sciences that offer therapies to treat the deadly SARS-CoV-2 virus, are predictably

dead set against waivers. They have maintained relentless pressure on Washington not to yield at WTO.

The use of march-in rights, embedded in the US law, is the new front against Big Pharma.

In a detailed letter to Becerra, the Make Meds Affordable group has underlined the crushing effect of high drug prices on the lives of Americans. It says one in four Americans, especially in the "black and brown communities", is unable to afford drugs and have to make "impossible choices between medicines and other necessities".

Reminding Becerra that he has the power under existing law to expand affordable medicine access, the group has called on him to override patent rights on six important therapies for cancer, COVID-19, HIV, Hepatitis C, diabetes and asthma that critics claim are too costly for patients to afford. Exercising such executive powers could be transformative for public health.

The lot of millions of Americans is pretty dismal, because they pay 2.5 times more for prescription drugs than people in other countries. In fact, pharma giants earn more profits from the sale of the 20 top-selling drugs in the US than from the rest of the world.

Make Meds Affordable argues that once monopolies end, robust generic competition can bring prices down. A study by the US Food and Drug Administration has found that allowing just six generic



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producers to enter the market can lead to price reductions of 95 per cent.

Sensing the threat posed by Make Meds Affordable's demand, pharma companies have rallied to squelch any action by Becerra. They have put together a large counter-attack group of IP lawyers, academics and R&D organisations to warn that dismantling the IP system would weaken the "strong, predictable" patent protections they claim are critical for the fast development of new COVID-19 vaccines and drugs.

In India, where the situation may not be similar, the government has been reluctant to use the flexibilities in the patent law to make COVID-19 drugs despite the nudging of the court.

In an affidavit filed in the Supreme Court, the

Narendra Modi government said it preferred to opt for voluntary negotiations with the drug manufacturers instead of resorting to compulsory licenses (CL) although these are TRIPS-compliant. It said the use of CL "can only prove to be counter-productive at this stage".

The pusillanimity was obvious. It said "any discussion or a mention of exercise of statutory powers either for essential drugs or vaccines having patent issues would have serious, severe and unintended adverse consequences" on India's efforts made on a global platform. The reference was to its TRIPS waiver plea at WTO. In the event, India has lost out twice over. Such is the power of the pharma industry.

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HK Avenue 19, Swastik Society, Navrangpura
Ahmedabad 380 009 INDIA

Tel: 91 79 2642 5258 / 5259 Fax: 91 79 2642 5262 / 5263 info@hkindia.com • www.HKINDIA.com

