Editorial

The 2020 Nobel Prize in Physiology or Medicine is awarded to Dr. Harvey J. Alter, Dr. Michael Houghton and DR. Charles M. Rice for the discovery of Hepatitis C virus. Hepatic inflammation and its symptoms are identified since long back and there was huge death due to this disease even after discovery of Hepatitis B virus. Then research of these three scientists discovers Hepatitis C virus which was the main factor of liver cirrhosis and liver cancer.

As per WHO Report, HAV infection caused 114 million cases of acute hepatitis in 2015, while 257 million people lived with chronic HBV infection and 72 million with chronic HCV infection in the same year. Due to their capacity to establish chronic infections, HBV and HCV are major causes of morbidity and mortality with 1.34 million deaths reported in 2015. Due to the pioneering work of these three scientists and their team who built upon their findings, validated tests that identify HCV carriers and allow the elimination of contaminated blood and blood products are broadly available around the world, and effective drugs have changed the fate of HCV infected patients. HCV induced hepatitis is now in many cases a curable disease. It is reported that short-term anti-viral treatment cures more than 95% of the patients, including advanced cases who failed to respond to previous therapeutic modalities.

Kudos to Dr. Harvey J. Alter, Dr. Michael Houghton and Dr. Charles M. Rice for their discovery which will save millions of lives.

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South Africa and India’s proposal to waiver recognition and enforcement of Intellectual Property Rights for COVID-19 Medical Technologies deserves universal support, but countries also have to take domestic measures

On October 2, India and South Africa petitioned the World Trade Organization (WTO) to allow all WTO members to bypass granting or enforcement of patents, trade secrets, industrial designs, and copyrights on COVID-19-related drugs, vaccines, diagnostics and other medical technologies for the duration of the pandemic – until global ‘herd immunity’ is achieved. The proposed “Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19” should be promptly and emphatically supported by governments, international institutions, global health initiatives, and all of civil society—from health workers, to academics, and access-to-medicines activists.

We should expect vociferous opposition from the biopharmaceutical industrial and its supporters from wealthy country governments who have been claiming (confusingly and inconsistently) that IP is essential to innovation and that IP is not a barrier to the pandemic response. But the world desperately needs freedom to expand production of COVID-19 health products, secure lower prices, and speed their equitable distribution to all corners of the globe.

Article IX 3 and 4 of the Marrakesh Agreement establishing the WTO clearly states that WTO Member States have the right to establish a waiver from the recognition or enforcement of intellectual property rights under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in exception circumstances like those presented by the COVID-19 pandemic. The conditions on the waiver and its time duration will need to be finalized, but there is no doubt that South Africa and India have presented well-grounded justifications for the proposed waiver. The TRIPS Council meets October 15-16 and could approve the waiver and forward it for decision to the Ministerial Conference in June 2021. Given the urgent nature of the proposal, the waiver proposal should be forwarded to the WTO General Council even before then for an earlier decision. There is ample precedent—multiple previous intellectual property waivers have been granted by the WTO, including a waiver on the enforcement of Article 31(f) of the TRIPS Agreement and waivers of certain obligations under Article 70(8) and (9). Although the preference at the WTO is to reach consensus, countries can force a vote and a three-fourths majority will pass the waiver.

The most compelling justification of the waiver is that intellectual property rights do in fact present significant barriers to the scale-up and diffusion of manufacturing capacity to produce sufficient quantities of vaccines, medicines, diagnostic tests, personal protective equipment, and other medical technologies needed to diagnose, prevent, treat, and cure COVID-19. Unfortunately, efforts to secure voluntary cooperation have thus far been unsuccessful. Although Costa Rica and 40 other countries convinced the World Health Organization to establish the COVID-19 Technology Access Pool, which would accept voluntary transfer of exclusive patents, data, and information rights and thereafter license those rights to qualified producers, no biopharmaceutical company has offered such rights over the past four months. The restrictive, flawed voluntary licenses negotiated by Gilead for remdesivir, and by Oxford and AstraZeneca on their candidate vaccine are shrouded in secrecy and exclude sales in many countries.

The world needs this waiver: because IPR barriers are real; because voluntary measures are insufficient; and because vaccine, therapeutic, and diagnostic nationalism is leaving medical cupboards bare in the Global South. The world also needs the waiver for symbolic reasons – too many countries have bought the message that the TRIPS Agreement stands in the way of prioritizing public health and that they are powerless. But the waiver proposal is a mighty tool that they can use immediately to free themselves from the shackles of IP and market fundamentalism that is leaving so many so far
behind. Passing the waiver will send a powerful message to industry that it should begin to share its technology voluntarily or it will be forced to do so involuntarily.

Countries must also take steps to implement the waiver domestically. Meanwhile, while countries sit on the sidelines and wait for voluntary relinquishment of IPRs by industry, rich countries have raced in and procured disproportionate supplies of promising medicines, vaccines, and diagnostics. As a result, low- and middle-income countries have had only 4% of the per person access to molecular diagnostic tests that rich countries have had. Likewise, the U.S. cornered virtually all of Gilead’s global supply of remdesivir through October 2020. And the U.S., U.K., E.U, and Japan, with just 13% of the global population, have negotiated advance purchases and options to purchase well over 50% of the projected global COVID-19 vaccine supply through the end of 2021.

However, the waiver will only open space for countries to act domestically. At a technical level, all the waiver will do is save countries from state-state dispute settlement under the TRIPS Agreement and provide authorization to take needed steps nationally. Countries must understand that the waiver is not self-effectuating, meaning that passing the waiver will not automatically empower countries to disregard nationally authorized intellectual property rights, rights established in existing patent, copyright, trade secret, and data protection laws. Countries will have to take resolute steps domestically to waive national recognition and enforcement of COVID-related intellectual property rights until immunity is achieved.

For details: https://healthgap.org/author/brook

**Blocking Immune system pathway may stop Covid-19: Johns Hopkins study**

As the world waits eagerly for an effective vaccine against the Covid-19 virus, researchers are also focusing on better understanding of how the virus attacks the body in the quest for other means of stopping its devastating impact.

The key to one possibility -- blocking a protein that enables the virus to turn the immune system against healthy cells -- has been identified in a recent study by a team of Johns Hopkins University researchers. Based on their findings published in the journal 'Blood', the researchers believe that inhibiting the protein known as Factor D will also curtail the potentially deadly inflammatory reactions that many patients have to the virus. Scientists already know that spike proteins on the surface of the SARS-CoV-2 virus -- making the pathogen look like the spiny ball from a medieval mace -- are the means by which it attaches to cells targeted for infection.

To do this the spikes first grab hold of heparan sulfate, a large, complex sugar molecule found on the surface of cells in the lungs, blood vessels and smooth muscle making up most organs. Facilitated by its initial binding with heparan sulfate, SARS-CoV-2 then uses another cell-surface component, the protein known as angiotensin-converting enzyme 2 (ACE2), as its doorway into the attacked cell. The Johns Hopkins medicine team discovered that when SARS-CoV-2 ties up heparan sulfate, it prevents Factor H from using the sugar molecule to bind with cells. Factor H’s normal function is to regulate the chemical signals that trigger inflammation and keep the immune system from harming healthy cells. Without this protection, cells in the lungs, heart, kidneys and other organs can be destroyed by the defence mechanism nature intended to safeguard them. "Previous research has suggested that with tying up heparan sulfate, SARS-CoV-2 activates a cascading series of biological reactions -- what we call the alternative pathway of complement or APC -- that can lead to inflammation and cell destruction if misdirected by the immune system at healthy organs," said the study’s senior author Robert Brodsky.

The APC is one of the three chain reaction processes involving the splitting and combining of more than 20 different proteins -- known as complement proteins -- that usually gets activated when bacteria or viruses invade the body.
In a series of experiments, the research team used normal human blood serum and three sub-units of the SARS-CoV-2 spike protein to discover exactly how the virus activates the APC, hijacks the immune system and endangers normal cells. They discovered that two of the sub-units called S1 and S2 are the components that bind the virus to heparan sulfate -- setting off the APC cascade and blocking Factor H from connecting with sugar -- and in turn disabling the complement regulation by which Factor H deters a misdirected immune response.

"We found that by blocking another complement protein known as Factor D which works immediately upstream in the pathway from Factor H, they were able to stop the destructive chain of events triggered by SARS-CoV-2," the authors wrote.

Source: Economic Times

**DCGI nod to Phase-1 human trials of 'antisera' with potential to treat Covid-19**

The Drugs Controller General of India has given permission for conducting Phase-1 human clinical trial for an "antisera" that was developed by injecting inactivated SARS-CoV-2 in horses and can be a potential treatment for COVID-19, ICMR officials said on Tuesday. The 'antisera' has been developed by the Indian Council of Medical Research (ICMR) in collaboration with a Hyderabad-based bio-pharmaceutical firm.

"With Biological E Limited we have developed an horse 'antisera' and we have just got clearance for conducting clinical trials for that," ICMR Director General Dr Balram Bhargava said at press briefing on Tuesday. The 'antisera' is yet to undergo human clinical trials to establish safety and efficacy.

Antisera are blood serum high in antibodies against specific antigens and are injected in humans to help kickstart the immune system to fight specific infections.

"The ICMR and Biological E Limited, Hyderabad, have developed highly purified antisera (raised in animals) for prophylaxis and treatment of COVID-19," the apex health research body had earlier said in a tweet.

The pre-print version of the study regarding the development of the equine antisera has been posted on the Research Square platform.

For details: ET Health world.com

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**Congratulations!**

Dr. Rao VSV Vadlamudi for being reelected as the President of Commonwealth Pharmacists Association (CPA)

Mrs. Manjiri Gharat for being elected as Vice President of International Pharmaceutical Federation (FIP)

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