Crisis-Analysis Intellectual Process Findings From the COVID-19 Pandemic

Syed Afroza,D.Kumar
Dept of CSE
Dr.Samuel George Institute of Engineering & Technology, Markapur, India

Abstract

The massive outbreak of COVID-19 brought the whole world to its knees. It also exposed the existing inequalities of income, age, race, sex and geographical location etc. which led to the disproportionate impact of the pandemic on the vulnerable sections of the global society. This dismal picture of the global healthcare system has a lot to do with inadequate and indiscriminate access to medicines, Covid testing kits, vaccines and other facilities. A related pertinent issue that came to light was the scuffle between IP and access to affordable medicines, vaccines and other crucial medical technology. It is worth mentioning that the debate between IP and access to medical technology has been going on for a long time, coronavirus only intensified it. In this article, the author will take you through the impact of IP on access to medical technology in times of a pandemic including what can be done to become future-ready.

Introduction

1.IP and COVID-19

Intellectual Property is all about innovation and ideas and IP law deals with protecting these innovations and incentivising them. The WTO defines IP rights as the rights given to people for what are called "creations". Intellectual property rights give a monopoly to the creator over their ideas for a specified duration and enable them to prevent others from using their creations and to negotiate payment in return for permission to use them. The developers of new technologies thus have the exclusive right to exploit their innovations during the period of such protection and are free to charge any price to cover their R&D costs and earn huge profits as well. The owner of a patent has the exclusive right to his invention and others are stopped from conducting research and manufacturing or distributing such patented products or processes.

Now, one might think, what IP has got to do with Covid-19? Well, the answer is almost everything. IP, particularly patents are an intrinsic aspect when we talk about global healthcare or dealing with pandemics. In the context of Covid-19 as well, vaccines, medical equipment, software apps, tracking systems, diagnostics and other innovations etc. have critical IP implications. The response to a pandemic is inextricably linked to IP as the development of vaccines and other medical technology constitutes an important part of public health preparedness.

1.1 TRIPS agreement and COVID-19

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994 is the most comprehensive international level multilateral agreement on intellectual property that deals with the

protection of intellectual property rights such as patents and trademarks.

Article 28 of the TRIPS Agreement grants exclusive rights to a patent holder to prevent others from producing, using or selling the patented product without their consent. Article 33 provides that the term of protection shall normally extend to 20 years from the date of filing.

It is pertinent to note that the TRIPS agreement contains certain flexibility provisions which provide for exceptions where the WTO members can permit the use of patents without the authorisation of the patent holder such as in case of extreme urgency or public non-commercial use and protection of human/plant/animal life. With regard to pharmaceutical drugs, nations have time and again resorted to compulsory licensing. Compulsory licensing is when a government allows a third party to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself.

Are flexibility provisions of the TRIPS agreement sufficient to deal with a pandemic

The plain answer to this question is No. According to Dr.Hyo Yoon Yang, the compulsory licence provisions under Article 31 of the TRIPS agreement have proven insufficient:

- To tackle already existing and emerging patent thickets and data exclusivity rules that impede production by the manufacturers other than the IP rights holders.
- They do not address the need for transfer in technology and sharing know-how needed to build local and regional manufacturing capacity.
- They do not cover copyright, undisclosed information and trade secrets.

Also, it is noteworthy that at the time when the TRIPS agreement was formed, about 94% of the global research and development was being conducted in developed countries only, the developing countries accounting for a minimal 6% only. The TRIPS Agreement thus ignores the basic premise that intellectual property cannot be expected to have the same effect in developed and developing economies.

1.2 Is patent law ill-suited to a pandemic

The patent law forms an important part of a country's national innovation system as it encourages technological progress and innovation. However, during the pandemic, we witnessed some uncertainty and confusion around IPR in relation to medical technology which hindered the effectiveness of research and development of crisis critical products. Hence, the patent law while boosting technological progress and innovation in normal times somewhat failed to deal with the emergency conditions of a pandemic. Patent law encourages the creation of new ideas for the long run by slowing their dissemination in the short run. Such a premise becomes futile when you have an ongoing pandemic that requires accelerated production and dissemination of medical technology, essential drugs and equipment.

Waiving patent rights for COVID-19 vaccine

The proposal for temporarily waiving IP and patent rights for COVID-19 vaccines was first introduced at the WTO by India and South Africa in October 2020 and was then co-sponsored and supported by many low-income countries. The proposal was opposed by the USA and the European Union. However, on May 5, 2021, the USA reversed its stand and agreed to back the proposed waiver, a move that received mixed reactions.

Vaccine patent

Patents give the vaccine developers exclusive right to manufacture the shot developed by them. This also gives them full discretion to charge any price for covering their R&D costs and making significant profits as well.

Why patent waiver

The idea behind proposing a waiver is to suspend the rights of pioneering vaccine companies to enforce their patents and enable the generic manufacturers to make the vaccine, without the fear of being sued. This would lead to the manufacturing of vaccines in developing countries, thereby fostering the vaccination drive.

Is waiver a solution

Those against the waiver of patents on COVID-19 vaccine argue that removing or suspending the patent enforcement would disincentivize the pharma companies to invest and innovate in the research and development of vaccines. It is also argued that waiving patents is not the solution for coping with the shortage of vaccines as the major obstacle is the lack of infrastructure in developing countries to manufacture the vaccines and other crucial medical equipment. Also, waiving patents is a redundant measure when compulsory licensing is already permissible.

According to Thomas Cueni, director-general of the International Federation of Pharmaceutical Manufacturers and Associations, "*Patents, and IP more generally, are the main reason that there is such a strong innovation base to work from to find solutions… there is no guarantee of success as few treatments and even fewer vaccines may prove to be safe and effective. This level of risk-taking would be impossible without a flourishing innovation ecosystem built on strong IP incentives*."

2.0 Getting ready for the future

International cooperation

International cooperation between governments and public-private institutions etc. can play an important role in improving access to the technology needed to produce crisis-critical goods such as mass ventilators, testing kits and other equipment in the case of COVID-19.

In May 2020, WHO launched international cooperation and collaboration among countries and various institutions through its 'Solidarity Call to Action' to realise equitable access to COVID-19 health technologies through a pooling of knowledge, intellectual property and data. WHO urged the Governments and other R&D funders to take action for promoting innovation and facilitating open sharing of knowledge, intellectual property and data necessary for prevention and treatment of COVID-19. Another such measure of international cooperation and collaborative effort is the 'Open Covid Pledge', a pledge to share IP in the fight against Covid and

for encouraging the development of cures for COVID-19 by making IP relevant to COVID-19 freely available.

2.1 Voluntary initiatives

Many organisations, institutions and corporations undertook collective efforts and voluntary initiatives to resolve the difficulties posed by the pandemic. Some of the initiatives taken by private players to improve R&D and access Covid related equipment and medicines are as follows:

1. Use of open licensing models collaboratively to develop hardware for resolving supply chain weakness;
2. Commitment to non-exclusive and royalty-free licensing;
3. Publication of scientific data on a free-to-use basis and free access to other copyrighted scientific literature ;Publishing of technical specifications of vital equipment such as ventilators;
4. Knowledge sharing that allowed others to manufacture and access technologies;
5. Permission to use text and data-mining and machine-learning technologies;
6. Free access to patented technologies and protected designs related to diagnosing, preventing, containing and treating COVID-19.

2.2 Public health emergencies and direct government support

IPR recognises the efforts of the crucial stakeholders who take huge risks to bring innovations to the forefront by allowing them to reap the benefits of incurring huge costs in R & D with no sure chance of success. For example, A patent holder can restrict others from accessing the patented technology without his permission and can permit the same by charging any costs. A patent holder gets the exclusive right to his creation for a specified period (20 years in the USA and India). Patent rights thus slow the pace of diffusion of a new invention by restricting output, blocking competitors and raising prices. This is essential to foster innovation and the development of advanced technology. But this cost and benefits approach of patents is of no help in times of a global emergency like the ongoing pandemic. In present times, our goal is to accelerate the process of vaccination and not to slow it down.

However, this poses a significant question. If patent protection should be taken away in times of a global health emergency, then how to incentivise the drug makers to undertake the huge R&D costs for developing vaccines and other medical technology while taking away their exclusive rights over the production and sale of such technology?

One of the ways to tackle this is through direct government support including public funding of research and development and the making of purchase commitments by the government in advance to buy large numbers of doses at set prices, offering huge profits and paying the drug companies generously etc. Thus, providing superior incentives to pharmaceutical companies as compared to those available under the patent regime in normal times will be a preferable solution.

3.0 Flexibility in the IP system

The IP challenges faced during the Covid-19 pandemic have further stressed the importance of well functioning IP systems which would consider the needs of a wide range of stakeholders including research and development institutions, start-ups, investors and most importantly of the public at large who ultimately benefit from the innovation. However, the implementation of such a regime is not at all easy to achieve. This would require significant amendments in the domestic IP framework, including the implementation of the provisions of the TRIPS Agreement that provide flexibility for public health purposes and their application under national law. The IP regime provides for certain exceptions to patent **rights** for supporting access of countries' to medical technology and innovation. The inclusion of a research exception in the domestic IP laws where it is currently absent can be resorted to as well. In countries where research exception is available under domestic laws, the research and development on the patented Covid-19 technology do not constitute patent infringement. Also, a regulatory review exception permits the use of patented technology without obtaining the consent of the patent holder to develop information to obtain regulatory marketing approval. Compulsory licences and government-use licences are other available measures that prove beneficial in this regard.

Conclusion

Prof. Carlos M. Correa has rightly said that *"IP is not a magic tool. It is not just by implementing patent law that we will promote innovation. It would depend very much on the particular conditions, infrastructure, research and development capacity and industry profile of a country"*. There are concerns that IPR is giving more room to technology holders to retain technology and to not share it. Such a stance might not be suitable in the situation of a pandemic. There can never be a choice between profits and people. IPR has to give way to greater concerns and public health goals. Thus, a major reform in the IP regime is much called for to ensure the structuring of incentives in such a way that the profit-seeking motives of drug companies and global public health goals are well aligned.

REFERENCES

[1] Mortality Analyses, Johns Hopkins Coronavirus Resource Center. Accessed: May 11, 2020. [Online]. Available: https://coronavirus.jhu.edu/ data/mortality

[2] Worldometer, Worldometer COVID-19 Pandemic, Worldometer. Accessed: May 12, 2020. [Online]. Available: https://www.worldometers. info/coronavirus/?utm_campaign = homeAdvegas1?%22

[3] C. ¸ Stef˘anescu, I. Petrescu, and A. Munteanu, "Intellectual property in critical conditions," in Proc. WSEAS 3rd World Multiconf. Appl. Econ., Bus. Develop, WSEAS Press, 2011.

[4] S. Chopra and A. Negi, "Role of intellectual property during recession," J. Intell. Property Rights, vol. 15, pp. 122–129, 2010.

[5] B. W. Jacobs, "Using intellectual property to secure financing after the worst financial crisis since the great depression," Marqette Intellectual

Property Law Rev., vol. 15, pp. 450–464, 2011.

[6] J. M. Champagne, “Access to essential medicines in developing countries: the role of international intellectual property law & policy in the access crisis,” Albany Law J. Sci. Technol., vol. 22, pp. 75–101, 2011.

[7] D. Halbert, “Moralized discourses: South Africa’s intellectual property fight for access to AIDS drugs,” Seattle J. Social Justice, vol. 1, no. 2, 2002, Art. no. 2.

[8] J. A. Harrelson, “TRIPS, pharmaceutical patents, and the HIV/Aids crisis: Finding the proper balance between intellectual property rights and compassion,” in Proc. Widener Law Symp. J., 2001, vol. 7, pp. 175–201.

[9] M. Childs, “Towards a patent pool for HIV medicines: The background,” Open AIDS J., vol. 4, pp. 33–36, 2010.

[10] K. L. Cox, “The medicines patent pool: Promoting access and innovation for life-saving medicines through voluntary licenses,” Hastings Sci. Technol. Law J., vol. 4, no. 2, pp. 293–326, 2012.

[11] A. Krattiger, S. P. Kowalski, R. Eiss, and A. Taubman, “Intellectual property management strategies to accelerate the development and access of vaccines and diagnostics: Case studies on pandemic influenza, malaria and SARS,” pp. 67–134, 2006. [Online]. Available: https://scholars.unh.edu/law_facpub/201/

[12] A. Berkman, “The global aids crisis: Human rights, international pharmaceutical markets and intellectual property,” Connecticut J. Int. Law, vol. 17, 2001, pp. 149–155.

[13] B. Reiter, “Theory and methodology of exploratory social science research,” Int. J. Sci. Res. Methodol., vol. 5, no. 4, pp. 129–150, 2017.

[14] Ø. Pålshaugen, “How to generate knowledge from single case research on innovation?” Int. J. Action Res., vol. 5, no. 3, pp. 231–254, 2009.

[15] M. Barzelay, “The single case study as intellectually ambitious inquiry,” J. Public Admin. Res. Theory, vol. 3, no. 3, pp. 305–318, 1993.

[16] T.Wang, F. Tietze, and R. Phaal, “Intellectual property strategy development through roadmapping,” in Proc. R&D Manage. Conf., Milan, Italy, 2018, pp. 1–17.

[17] T. Wang, F. Tietze, R. Phaal, and N. Athanassopoulou, “Roadmapping for strategic management of intellectual property,” in Proc. R&D Manag. Conf., Leuven, Belgium, 2017.

[18] WHO, “Coronavirus disease (COVID-2019) R&D,” WHO. Accessed:

Apr. 3, 2020. [Online].Available: http://www.who.int/blueprint/prioritydiseases/
key-action/novel-coronavirus/en/
[19] "Why is Germany able to test for coronavirus so much more than
the UK?" Reaction, (Mar. 31, 2020). Accessed: Apr. 3, 2020. [Online].
Available: https://reaction.life/why-is-germany-able-to-test-forcoronavirus-so-much-more-than-the-uk/
[20] "Ventilator challenge UK consortium," Penlon. Accessed: Apr.1, 2020. [Online]. Available: https://www.penlon.com/Blog/March-2020/
Ventilator-Challenge-UK-Consortium
[21] "Cobra biologics is proud to be part of a consortium to rapidly develop
a COVID-19 vaccine. Accessed: Apr. 3, 2020. [Online]. Available: https://www.outsourcedpharma.com/doc/cobra-biologics-proudto-be-part-of-a-consortium-rapidly-develop-covid-vaccine-0001
[22] "Towards a drug against COVID-19 | Co-led by Dr.Nir London,
global consortium aims to accelerate drug development,"
WeizmannCompass, (Mar. 30, 2020). Accessed: Apr. 3, 2020.
[Online]. Available: http://www.weizmann.ac.il/WeizmannCompass/sections/briefs/towards-a-drug-against-covid-19
[23] "Here are some drugs that may be repurposed to treat coronavirus,"
NBC News, Accessed: Apr. 3, 2020. [Online]. Available: https://www.nbcnews.com/health/health-news/here-are-some-existingdrugs-may-be-repurposed-treat-coronavirus-n1162021
[24] Clover and GSK announce research collaboration to evaluate
coronavirus (COVID-19) vaccine candidate with pandemic adjuvant
system | GSK. Accessed: Apr. 3, 2020. [Online]. Available: https://www.gsk.com/en-gb/media/press-releases/clover-and-gskannounce-research-collaboration-to-evaluate-coronavirus-covid-19-vaccine-candidate-with-pandemic-adjuvant-system/
[25] N. Media, "Novartis and others in 'unprecedented' COVID-19 partnership,"
Life Sci. IP Rev., Accessed: Mar. 30, 2020. [Online]. Available: https://www.lifesciencesipreview.com/news/novartis-and-othersin-unprecedented-covid-19-partnership-3971

student details:

name: Syed Afroza

mail: affusyed98@gmail.com

Dr.Samuel George Institute of Engineering & Technology, Markapur, India,AP

guide details:

D.Kumarreceived B.Tech (CSIT) Degree from JNT University in 2006 and M.Tech (CSE) Degree from JNTUK Kakinada in 2011. He has 11 years of teaching experience. He joined as Assistant Professor in Dr.Samuel George Institute of Engineering & Technology, Markapur, India in 2006. Presently he is working as Associate Professor in CSE Dept. His Interested research areas are Image Processing and Computer Networks. He attended Various National Workshops and Conferences.