



Intellectual Property Rights and Innovation in the Times of Corona Epidemic

Introduction

The global health crisis on account of Corona Epidemic has rekindled debate on use of IPRs as incentives as well as constraints for access to medicines. There are parallels with the debate on access to medicines and right to health on account of HIV/AIDS but this time the issues are not that simple. While research teams across the globe are racing against the time to find a cure whether with vaccines, use of drugs used to treat HIV/AIDS or through a combination of drugs, the crisis is worsening day by day, hour by hour. Right now, there are rays of hope, promising pathways of discovery and treatment and renewed thrust in terms of investment and efforts. According to one source more than 41 research groups and companies are working to produce vaccine.¹ As of now there is no vaccine available as a protection against Covid-19. There are identified therapeutics and WHO has listed them under different categories.² At the same time, it is important to understand that we do not know everything about Covid-19 and whether this will result in seasonal diseases like flu or will be contained successfully to such an extent, or that it will not be a menace in the future is not yet known. Whatever it is, there is no doubt that this is a pandemic and has emerged as a major public health issue, particularly because of its spread across the globe and rapidly increase in deaths. Recently many NGOs and academics have urged the Director-General of World Intellectual Property Organization to show leadership and ensure that IP rights and

regulation do not become barriers to access and innovation.³

WHO lists, *inter alia*, products/candidates that were used for, other diseases such as, Malaria, HIV infection, including, Corticosteroids, Chloroquine, Ritonavir + Lopinavir (Kaletra), Ribavirin + Ritonavir + Lopinavir, Emtricitabine + tenofovir (Truvada), and, Baricitinib (Olumiant or Baricinin). Under the large scale global trial, called SOLIDARITY, WHO is giving emphasis on four therapies that are considered as most promising. These are Remdesivir, an antiviral compound, chloroquine and hydroxychloroquine used in treatment for Malaria, combination of lopinavir and ritonavir (HIV drugs), and, a combination of lopinavir and ritonavir with interferon-beta.⁴ Gilead developed Remdesivir, initially for viral infections including Ebola and Marburg virus. According to Knowledge Ecology International (KEI), it was developed with significant support from US government. It has been extensively patented, including in India. Which among these is the best from a public health perspective depends upon the context and the status of patents and patent applications. Just as Covid-19 is making us rethink many assumption and policies on our capacity to handle pandemics, this issue of innovation and access also calls for a rethink and imaginative solutions. In this policy brief, an analysis of the issues and approaches in finding solutions is provided.

RIS Policy Briefs are prepared on specific policy issues for the policymakers.

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- ¹ <https://sciencebusiness.net/news/race-covid-19-vaccine>
- ² https://www.who.int/blueprint/priority-diseases/key-action/Table_of_therapeutics_Appendix_17022020.pdf
- ³ <http://infojustice.org/archives/42220>
- ⁴ <https://www.sciencemag.org/news/2020/03/who-launches-global-megatrial-four-most-promising-coronavirus-treatments>
- ⁵ Cynthia Ho 2011, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, Oxford: Oxford University Press
- ⁶ Reto M. Hilty , Kung-Chung Liu (Eds) 2015 *Compulsory Licensing: Practical Experiences and Ways Forward* Cham: Springer
- ⁷ WTO http://www.wto.org/english/tratop_e/trips_e/public_health_fa_q_e.htm
- ⁸ WIPO 2019 *COMPILATION OF VARIOUS LEGAL PROVISIONS ON COMPULSORY LICENSES AND GOVERNMENT USE* Geneva: WIPO https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-appendix1.pdf
- ⁹ <https://www.gilead.com/-/media/gilead-corporate/files/pdfs/company-statements/remdesivir-orphan-drug-designation.pdf?>

TRIPS, Patents and Compulsory Licensing

With TRIPS becoming the de facto standard for IP rights in most countries of the world, the options for regulators and policy makers are circumscribed by TRIPS.⁵ Although TRIPS does provide flexibilities, these are subject to conditions. But more important is that for countries that have limited manufacturing capacity and regulatory capacity, their availability under the law alone will not guarantee that access to medicines will be enhanced. Rather countries should have the capacity to make the best use of them and translate that in terms of strategies that will result in better access to medicines at affordable prices. Among the TRIPS flexibilities, use of Compulsory Licensing is the most relevant measure and the one has been used before and after TRIPS extensively.⁶ According to WTO; “Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO’s agreement on intellectual property - the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.”⁷

Compulsory Licensing is an option when patent holders are unwilling to supply the requisite goods in adequate numbers or are not interested in commercialising the innovation despite there is a need or the patent rights are abused to maximise profits. The Trade Related Intellectual Property Rights (TRIPS) Agreement enables governments to issue Compulsory Licenses (CL) subject to certain conditions, as specified in Article 31. Many countries have used CL under different circumstances and there is enough case law and there are enough laws to show that CL has been effective, particularly in enhancing access to drugs in HIV/AIDS. Basically, by issuing CL government ‘breaks’ the rights of the patent holder but ensures that royalty is being paid. Although terms and conditions vary, many nations have provisions on issuing CL and government use.⁸

Israel issued CL on 23 March for lopinavir/ritonavir, used as HIV medicine and now used in many countries to treat patients suffering from Covid-19. Under this, the import of lopinavir/

ritonavir from a generic producer is permitted. The Parliament of Chile passed a resolution requesting the Government to declare that CL for a wide range of medicines, products and devices useful in, *inter alia*, prevention, diagnosis treatment and detection of the virus in Chile. Similarly, the National Assembly of Ecuador has passed a resolution requesting the Health Minister to bypass patents related to medicines for Covid-19. UK and Germany are some of the other countries that may use provisions that grant the right to limit the rights of the patent holders or permit the government to use the patents. But companies are also facing the pressure to respond responsibly and not to use the current crisis to maximise their profits. Facing the heat, Gilead requested the FDA, to drop the special status for Remdesivir, as an orphan drug. Giving up that status means that it will forego the exclusivity for seven years that was granted earlier.⁹ On the other hand, how Gilead will ensure affordable access is yet to be known. In the days to come, as many governments may contemplate measures such as issuing CL, industry may face more pressure to prioritise public health over profits and work with governments in ensuring affordable access.

Although CL is an option under TRIPS, there are limits to its usage and scope for invoking it. Governments can declare the Covid-19 as a public health emergency and invoke CL and also allow parallel imports of the needed medicines, diagnostic kits, medical devices and vaccines. But the larger question is whether there is adequate capacity among the producers of generics to meet the demand within the country as well as to export. For many countries that have limited capacity and rely largely on imports of generics, the Paragraph 6 solution, which since has been incorporated in TRIPS as, Article 31bis, will be useful and invoking it they can import generics. As Article 31bis relates to export-oriented CLs its use is an opportunity for many developing countries/LDCs to enhance access.

In case of HIV/AIDS, CL was used by many countries and it could be used as an effective tool, on account of factors like the world recognising the gravity of the situation in many countries and availability of generics from many sources. Moreover, most of the countries that issued CL

also had capacity to produce generics. But how effective will CL be, when there is no vaccine against Covid-19 and there is lack of clarity on using lopinavir/ ritonavir for treatment? The treatment regarding HIV/AIDS was well established and the efficacy of the medicines and their combinations were known. This in turn helped both countries and generics industry to know the demand and produce/import medicines in adequate quantities. As these medicines have to be taken continuously, the demand and supply aspects can be anticipated and production and distribution can be planned. In case of Covid-19 these aspects are not clear and more importantly what combination of medicines will be more effective is yet to be ascertained.

Still not withstanding such uncertainties, countries should focus on using CL as an effective tool and explore all the options available to them under TRIPS and under national laws on health. In these times of crises and health emergencies, CL should be used to the maximum so that treatment and availability/supply of medicines is not hit by TRIPS or IP regimes. To encourage use of CL, all countries can pledge that while they will support application of CL, they will not use any other trade instrument or policy to discourage use of CL or as a factor in assessing adherence to IP rules, whether under TRIPS or under any other bi-lateral/ multilateral treaty. In other words, there should be a waiver on all restrictions on use of CL for use in actions relating to Covid-19. G20 should take a lead in this and arrive at a consensus.

Another key issue is that of TRIPS Plus provisions in Free Trade Agreements/Regional Trade Agreements/Bi-lateral Trade Agreements and these have the potential to reduce affordable access. When combined with Investment Protection Treaties, wherein IP is covered under Investment, there can be adverse impact on access to affordable medicines as well as to local production.¹⁰

Compulsory Licensing in India

CL can be issued invoking the powers vested through Section 84. Section 84 states that an interested party can apply to the patent office seeking CL on any one of the three grounds,

viz. unmet demands, lack of local manufacturing and unmet demand. Such an application can be made from three years after the date of grant of patent, if the efforts to obtain a voluntary license do not fructify.

The Patent Act provides three more options:

- 1 Government can acquire the relevant patents under Section 102 for public purpose. The price of the patents has to be negotiated between the government and patentee. However, if they fail to agree on this, the High Court can fix the price for the patent(s).
- 2) Under Section 100, Government can authorise use of any patent or patent applications for “purpose of government” by specific companies. Under this authorisation, manufacturing can be commenced without waiting for negotiations with patent holders to be completed. If no agreement is reached with the authorised user or government, the high court can fix the royalty payable.
- 3) Under Section 92, the Government can declare a national emergency and in these circumstances on account of Covid 19. It can notify the relevant patents and any interested person who intends to manufacture can apply to the Controller of Patents to issue a Compulsory License without going through the regular procedure and thereby get the License and start manufacturing. The reasonable royalty will be fixed by the Controller of Patents. In 2012, a CL was granted to Natco to produce an anticancer drug (Sorafenib) on the ground that the patent holder (Bayer AG) was found wanting in making it available to citizens of India. The generic version was just one fourth of the price of Sorafenib sold by Bayer.

While issuing CL seems to be the best option, it need not be so in some circumstances, particularly when the period between application for issue of CL and that of grant of patent is less than three years. Taking in to account the patents granted in India and patent applications pending on Remdesivir, and, Favipiravir, Gopakumar and Prathibha argue that the Government will have to choose from the above mentioned, last three options and act.¹¹

¹⁰ Gleeson et al. 2019, Analyzing the impact of trade and investment agreements on pharmaceutical policy: provisions, pathways and potential impacts, Globalization and Health 15(Suppl 1):78 <https://doi.org/10.1186/s12992-019-0518-2>

¹¹ Drugs That Could Be Used to Beat COVID-19 Have Another Barrier – Patents <https://thewire.in/law/remdesivir-favipiravir-covid-19-patents-indian-patents-act-ustr>

¹² <http://ipindia.nic.in/writereaddata/Portal/ev/sections/ps157a.html>

¹³ I thank Dr.V Siddhartha for pointing out this option and on invoking Section 157(a).

But under Section 157A the Government is empowered to take any action in the interest of security of India. According to this section:

“Notwithstanding anything contained in this Act, the Central Government shall:

- (a) not disclose any information relating to any patentable invention or any application relating to the grant of patent under this Act, which it considers prejudicial to the interest of security of India;
- (b) take any action including the revocation of any patent which it considers necessary in the interest of the security of India by issue of a notification in the Official Gazette to that effect.

Explanation. For the purposes of this section, the expression “security of India” includes any action necessary for the security of India which-

- i. relates to fissionable materials or the materials from which they are derived; or
- ii. relates to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment; or
- iii. is taken in time of war or other emergency in international relations.”¹²

Security can be broadly defined and the Government can invoke this section also. The Government can incentivise the patent holders/ drug companies to manufacture in India for export.¹³

Invoking CL citing public health emergency and making amendments through an ordinance to enable issue of CL even in cases when the period between application for CL and date of grant of patent is less than three years may be a better option. This is because in terms of theory and practice CL has been a preferred solution and there are rulings and precedents on this. The objective of enabling generics production quickly will be better served. Acquiring patents will send wrong signals to innovators, while invoking “purpose of government” will also

be seen as a step that will be perceived as a bad precedent. In case of CL the rights of the patent holder are impacted but only in a limited way. On the other hand, issue of CL to more than one party and issue of more than one CL can effectively incentivise production of generics.

Another option is to use the Competition law so that there is no monopoly and unfair pricing coupled with anti-competitive practices and there is competition. In invoking competition law, governments can use them in conjunction with rights available under Patent law. For example, a government can use the provisions to issue CL and also use competition law provisions to probe anti-competitive behaviour. But as not many countries have strong laws on competition and restriction of monopoly, this crisis may be used to revisit this issue.

Thus, there are options available under the IP and Competition Law regime to ensure that medicines are produced and made available. In combination with DPCO, the prices can be fixed and competition can be ensured. If necessary, in order to meet urgent needs and to assure regular supply, the government can even permit imports of these drugs and as a matter of policy, can exempt them from rules of tariffs and customs duties.

Many countries allow IP protection for second use of a drug, it is not surprising that second use claims have been applied for. For example, it has been reported that The Wuhan Institute of Virology of the China Academy of Sciences, has applied a patent for using Remdesivir, as a treatment for Covid-19. Remdesivir was originally developed by Gilead as an antiviral drug. If granted such patents can constraint access to the much-needed treatment as even if the earlier patent for the first use, say as an antiviral drug has expired, the second use claim will still be enforceable. Moreover, even if CLs have been issued in the case of the drug, those would be applicable only for the patent(s) covering the first use claim(s). The global status of such claims on the chemicals/compounds that are potential therapeutics is not clear. On the other hand, as India does not recognise such claims as patentable claims, there will not be any constraint on that ground. However, the problem may be acute for countries that allow

such claims and do not have indigenous capacity for production of generics. So even if they want to use CLs that may not be the perfect solution. In such cases, depending upon the national laws and regulations, grounds like government use, public health emergency have to be used to authorise imports. Whether to apply for a patent for second use is a good strategy or not is being debated. According to Enrico Bonadio, this is a flawed strategy and instead of that, The Wuhan Institute should have insisted on CL as a solution, rather than applying for a second use patent.¹⁴

Thus, even as the scientists are racing to find solutions, IP is becoming keenly contested topic. Whether IP will emerge as a major constraint in providing affordable access or not is not yet known. However, as there are precedents like HIV/AIDS crisis, which alerted the world on the issue of affordable access, lessons learnt from them will be useful in addressing the issues and finding solutions.

Patent Pools

In wake of this epidemic, seeking to widen access to products and treatments, the Costa Rica government has proposed that World Health Organization should create a voluntary pool for patent rights, test data and information that can be shared for developing drugs, diagnostics.¹⁵

This proposal envisages: “This pool, which will involve voluntary assignments, should include existing and future rights in patented inventions and designs, as well rights in regulatory test data, knowhow, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines. It should provide for free access or licensing on reasonable and affordable terms, in every member country. Given the urgency of this matter, Costa Rica proposes that the WHO develop an initial concise memorandum of understanding on the intent to share rights in technologies funded by the public sector and other relevant actors, and reach out to WHO Member States, non-profit institutions, industry and others, to sign such a MoU. The specific technologies and the terms of the assignments can be determined later, in the implementation stage of the pool, in consultation with R&D funders and rights holders.”

Patent pools have a long history and been used in different industries/sectors, either on a voluntary basis or by the order of the government. According to WIPO: “Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another or to third parties. Often, patent pools are associated with complex technologies that require complementary patents in order to provide efficient technical solutions. Generally, these patent pools cover mature technologies. Pools also frequently represent the basis for industry standards that supply firms with the necessary technologies to develop compatible products and services. In that case, they rather concern technologies that are yet to be fully developed.”¹⁶

In the last decade or so, a successful example of patent pooling has been Medicines Patent Pool (MPP). MPP is an initiative backed by United Nations. Initially it was focussing on creating patent pools for enhancing affordable access to HIV/AIDS medicines and later diversified its work to diseases like Hepatitis C. MPP has been able to offer affordable access with co-operation of industry, governments and other stake holders including philanthropic foundations. In light of the current epidemic MPP has decided to work on patent pooling to cover treatment for Covid-19. MPP has decided to support the call given by Costa Rica government. Earlier UNITAID has announced that it would commit, to begin with, \$30 million investment in treatment, diagnostics and tools.¹⁷ Recently, Director General of WHO has indicated in the media briefing on 6April “I support this proposal, and we are working with Costa Rica to finalize the details.”¹⁸

Both are positive developments. The earlier experience with HIV/AIDS indicates patent pooling works and can expand affordable access. When MPP was established, the treatment for HIV/AIDS was well established and the issue was that of expanding access and to make it affordable. In case of Covid19, how this work out is not clear. Although the MPP is a global patent pool, there can be other patent pools at national level and perhaps at the regional level. The different patent pools can complement each other and expand scope for affordable access. But a major challenge would be financing the pool. Given the adverse economic impacts of Covid19,

¹⁴ <https://www.sixthtone.com/news/1005210/why-patent-laws-matter%2C-even-in-times-of-crisis>

¹⁵ <https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf>

¹⁶ https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf

¹⁷ <https://unitaid.org/news-blog/with-special-investment-unitaid-bolsters-covid-19-response/#en>

¹⁸ <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---6-april-2020>

¹⁹ <https://www.nytimes.com/2020/04/01/world/europe/coronavirus-science-research-cooperation.html>

²⁰ <https://www.healthpolicy-watch.org/european-parliament-members-urge-open-licensing-for-covid-19-products-financed-through-eu-grants/>

²¹ See Jorge L. Contreras PATENT PLEDGES 543 Ariz. St. L.J 2013, SSRN Electronic Journal. 10.2139/ssrn.2309023 Ehrnsperger JF, Tietze F (2019) Patent pledges, open IP, or patent pools? Developing taxonomies in the thicket of terminologies. PLoS ONE 14(8): e0221411. <https://doi.org/10.1371/journal.pone.0221411>

it cannot be expected that the traditional donors and supporters of MPP will give this the first priority in funding. Moreover, for governments the first priority could be to find affordable solutions in health care than to finance a global patent pool.

Given the lack of wider options in terms of treatment, the governments may prefer to directly negotiate with the innovators and explore options like CL, patent pooling than enhancing access through a patent pool at the global pool. For countries that have both the financial resources and capacity to innovate this may be a preferred option as this enables them to address the problem directly and quickly. Another factor that is in favour of allocating resources for national level initiatives is that it sends a signal to the people that the government is taking the bull by horns. So, while some nations may prefer to work on their own and create pools at the national level, such an option may not be feasible for many countries, particularly LDCs. One solution to address the dilemma between supporting national pools and global pool is that governments can treat national pools and the global pool as complementary sources than as competitors.

Open Science and Open Innovation and Patent Pledges

Given the urgency to find effective solutions to the epidemic, governments and other stakeholders are focussing on accelerating the on-going efforts to find solutions and to fund and support new research and initiatives. In this there are discussions on using the solutions proposed earlier such as Health Impact Fund, Prizes and Advance Market Commitments. Using Open Source and Open Innovation, including Open Science approach and promoting freer flow of data and information among research groups have been suggested. It is worth pointing out that some of the solutions have been discussed earlier and the WHO

Similarly, options like patent pledges have been proposed now and using patent pledges are not new. In the last two decades are so, many such proposals have been made to address the need for newer approaches in incentivising

innovation for enhancing access to drugs and to develop and deploy technologies to address the climate change. For reasons of space we will not discuss them in detail but the point is despite many articles and reports, and, discussions not much has happened in these, in the sense that there have not been significant and large-scale initiatives based on these. Hence the possibility that discussions and proposed initiatives today may not get sufficient support in terms of financial and other resources is very much there. Still, this crisis also gives an opportunity to revisit the earlier proposals and modify them suitably.

According to Matt Apuzzo and David D. Kirkpatrick: “But the coronavirus has ignited the scientific community in ways that no other outbreak or medical mystery has before. That reflects the scope of the pandemic and the fact that, for many researchers, the hot zone is no longer an impoverished village in the developing world. It is their hometowns”.¹⁹ They point how researchers are collaborating and as they have realised that this is not a problem of developing countries or LDCs, only, the thrust is substantial although the vaccine may be years away. This thrust has been further strengthened by enhanced funding on R&D related to Covid-19. Developing countries like India have also launched special programmes to fund R&D and to incentivise commercialisation of relevant products. Thirtythree members of European Parliament have suggested that European Commission should prohibit exclusive licensing for Covid-19 products developed using grants from EU, besides asking for transparency in R&D so that affordability becomes a reality.²⁰

Patent pledges and covenants guarantee that innovators and users of technologies covered by the patents that are made available under the patent pledge and will not be sued for patent infringement as long as they fulfil certain terms and conditions. In this the patent holder neither puts the patents in public domain for free access and use to all and thereby abandons the rights, nor uses the patent solely for commercialisation purposes only. In the recent decades, the types of patent pledges have expanded and diversified and are now being practiced in, *inter alia*, software, green technologies and electronics.²¹ According to Chang and Stach: “Companies today increasingly are looking for ways to

maximize the value of their patents, and some are employing alternatives to the traditional direct monetization methods of patent licensing and assertion. These alternatives include agreeing not to assert patents offensively or to provide free patent licenses. ... In 1959, Volvo shared its three-point seat-belt patent. In 1974, General Motors similarly allowed others to use innovations in its catalytic converter. Tesla's move differs in that it made all of its patented technologies widely available, not just technology for any specific vehicle component"²²

In the context of Covid-19, an "Open Covid Pledge" has been launched so that IP related to Covid-19 is made widely available and is used extensively. Under this pledge companies, universities and others would provide free licenses to their patents, copy rights and few other property rights, to anyone for developing technologies related to diagnosis, prevention or treatment to Covid-19. The pledge is:

The pledgor grants to every person and entity that wishes to accept it, a non-exclusive, royalty-free, worldwide, fully paid-up license to fully use, practice and exploit all patent, copyright and other intellectual and industrial property rights (other than trademarks and trade secrets) that we have the right to license, for the sole purpose of ending the "covid-19 pandemic" and minimising the impact of the disease, including without limitation the diagnosis, prevention, containment, and treatment of the covid-19 pandemic."²³ Unified which calls itself as a "deterrence entity" has published its pledge which sets the terms and conditions of the pledge 'Open Covid Pledge'²⁴

To what extent patent pledges will work in this context is not clear. One issue is that if a technology is covered by many patents with different patent holders, more than anything else, unless the key or most important patents are pledged under "Open Covid Pledge" or any other similar pledge, patent pledges may not be an effective solution. If a major pharmaceutical company or a government join the pledge and make commitments then the idea of pledge will gain acceptance. But governments may not be keen to put patents for technologies developed with their funding under such a pledge as there is no incentive to join such an arrangement. A company can derive benefit

from patents pledged by others without pledging its own. As the pharmaceutical sector is very different from software and electronics, how effective this will be a question. Cross licensing and other approaches may be preferable when the technologies are not covered by too many patents and number of patent holders is less. As Richard Gold points out, there are models for sharing and collaborating in drug discovery and collaborative models and mechanisms should be harnessed so that the challenge is met effectively.²⁵

In mid-2000s and later, there was much discussion on Open Source Drug Discovery and a project in India was launched to use this model to develop drugs for TB. Although there is literature on Open Source Drug Discovery, there are not many successful projects or drugs developed through that approach. The reasons for that need to be explored so that we are able to find pragmatic solutions. Collaboration and open innovation are not uncommon in pharmaceuticals, particularly in biopharmaceuticals. But these have not made IP rights redundant, nor have resulted in open source drug discovery as an important model. Hence while there is enough scope to try open innovation and open source models, what will succeed is too premature to predict now.

It has been suggested that Health Impact Fund, Prizes and Advance Market Commitments can be used as alternative models to incentivise innovation. These ideas are not new and while it makes sense to recommend them as solutions, to us, the key issue is that of financing. Unless governments come together and form a consortium, and collectively fund or use one of these mechanisms, these ideas will remain what they are. But this is also the time to test novel approaches and schemes to incentivise innovation. Many of these models or approaches do not call for radical changes in IP laws and policies, nor call for relinquishing rights by IP holders. Hence, they deserve a relook and review.²⁶

Challenges for India

The global developments provide opportunities to India but there are also challenges. A major challenge is how India can meet the global needs for generics and domestic need, when on

²² Maximizing a Patent's Value by Pledging Not to Assert It? March/April 2015 By Jason E. Stach <https://www.finnegan.com/en/insights/articles/maximizing-a-patent-s-value-by-pledging-not-to-assert-it.html>

²³ <https://www.iam-media.com/copyright/new-patent-pledge-underlines-delicate-balancing-act-companies-must-strike-in-covid-19>

²⁴ <https://www.unifiedpatents.com/open-covid-pledge>

²⁵ <https://fortune.com/2020/03/26/coronavirus-vaccine-drug-development-open-science-covid-19-treatment/>

²⁶ As I intend to develop this further elsewhere, it is not explored fully here.

²⁷ Guerin PJ, Singh-Phulgenda S and Strub-Wourgaft N. The consequence of COVID-19 on the global supply of medical products: Why Indian generics matter for the world? [version 1; peer review: 1 approved] F1000Research 2020, 9:225 <https://doi.org/10.12688/f1000research.23057.1>

account of various factors there are significant constraints in availability of raw materials and organising production. It has been argued that “in the context of the COVID-19 pandemic, global reliance on Indian generics is likely to become a complex international challenge. There are no reliable substitutes for API supplies, nor production capacity available and more importantly, any country potentially capable of establishing manufacture is likely to focus on national needs and not on export nor development aid.”²⁷

It is estimated that India supplies about 20 per cent of the global generics and India's pharmaceutical exports are critical for programs on vaccination and on tropical diseases. While this indicates the importance of India in global public health, the epidemic has also shown that supplies could be limited or affected if the pharma industry in China is affected even for a month or two. The recent policy initiatives to reduce such a dependency and enhance local capacity to produce raw materials and ingredients like APIs could, in the long run, make India more self-reliant. But in the short term India has to find quick solutions.

Indian government should examine the challenges posed by IP laws and regulations. It should form a committee or working group to examine the issues in depth and come out with a policy to address them and to incentivise innovation. For example, in light of this crisis, the government can develop a coherent policy on using CL for meeting needs in India and to export drugs. Similarly, it can examine as to whether India has fully used the flexibilities under TRIPS and how they can be used in this occasion.

Regarding innovation, India should promote open innovation and open source drug discovery. It should examine the proposals earlier made and now, such as Prizes, Health Impact Fund, and, Advance Marketing Commitments and analyse which ones are suited to meet needs of India as an innovator and as a user of drugs. With WHO supporting the idea of Patent Pool, India should examine how to approach this and how it can contribute to that and benefit from that. It is suggested that a Working Group can be formed to monitor the developments and advice the government. Issues on access, affordability and incentivization have been discussed earlier also. In this new context, it is the right time to develop a coherent, pragmatic policy, that will enable India to meet the multiple challenges effectively and make significant contributions to global public health.

Conclusion

The HIV/AIDS crisis showed that the traditional IP rules and models of innovation do not assure affordable access. This resulted in some changes in IP rules and the recognition that IP and trade rules should not become major constraints for affordable access. The current crisis provides an opportunity to revisit and learn from the earlier one. This calls for a rethink of role of IP and its use as an incentive. The Business As Usual approach will not work. The current crisis should be seen as an opportunity to review and rethink and to give new models and approaches a chance. In the race against time, what we will do on IP and Innovation, may make a huge difference. The question is how much the governments, UN agencies and other stakeholders are prepared for this.

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