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Is the right to exclusivity a Hamlet question?¹ By Justice Prabha Sridevan

Today the judicial authority may be faced with balancing patent rights and patients' rights or right to life. It shall use all the tools at its command and innovate if necessary, but shall rule in favour of life.

There cannot be a better moment than now, the year of COVID-19, to place my argument, that the right to health and ergo the right to a life with dignity is way ahead of the right that the patented invention obtains to the owner. An open letter has been addressed by heads of States and others to the World Health Organization (WHO), "Our world will only be safer once everyone can benefit from the science and access a vaccine – and that is a political challenge....Now is *not* the time to allow the interests of the wealthiest corporations and governments to be placed before the universal need to save lives, or to leave this massive and moral task to market forces."² It is equally a judicial challenge. I argue that the right to life which logically means the right of access to medicine and the right to health, inheres in every human being and is not bestowed under any grant, and is unlimited by time. But the patent right is one granted by the State to the inventor as a quid pro quo allowing the owner to enforce and protect his right for a period at the end of which the owner shall transfer the technology and the invention comes to the public space.

The question. In a patent litigation between the right of access to medicine and the right to property, the judge must be the sentinel on the qui vive, not just a sentinel on the alert, but literally qui vive: "Who shall live" or "Whose side are you on"? Whose entitlement is heavier? Today when even the survival of the world as we know it today, depends literally upon who gets the medicine, I say the right to life is heavier.

Public interest is embedded in the patent statutes. Public interest is not an either-or factor in (India's) Patents Act. The General Principles mentioned in the Act as being applicable to working of patented inventions³, unmistakably mentions public health. The criteria for granting compulsory

¹ I thank Mr. Aravind Velu, Advocate, Madras High Court for his research assistance.

² See <https://thewire.in/world/unaid-world-leaders-covid-vaccine-letter>.

³ S.83
(a) ...

licence are also grounded in public interest⁴; compulsory licence can be granted in circumstances of national emergency and extreme urgency; and patents can be acquired by the State for a public purpose. Every country has similar provisions and they have been successfully employed both by the North and the South.

By creating a higher bar for determining non-obviousness, India made sure that incremental innovations did not get “canonised” as patents and its section 3(d) stands out as a model of how to use the flexibilities in a way that facilitates access to health⁵. The Supreme Court of India said “(W)e shall see how the Indian legislature addressed this concern and, while harmonizing the patent law in the country with the provisions of the TRIPS Agreement, strove to balance its obligations under the international treaty and its commitment to protect and promote public health considerations, not only of its own people but in many other parts of the world (particularly in the Developing Countries and the Least Developed Countries).”⁶ The State contracts with the patentee to enforce and protect the patent rights in return for technology transfer and promotion of technological innovation, for the benefit of not just the owner but also the user, and for the enhancement of social and economic welfare.

What about the economic entitlement? The argument of the patent rights holder is that, the exclusivity is the reward for the knowledge contributed to the world by their invention. And they must be allowed to recoup it. It is the “Money, money, money”⁷. It is argued that without monetary incentive there will be no innovation. It is argued that the owners have the right to maximise their profits. And since the creator’s right is a human right too and has been recognised as such, it is not bound to give way to right to health.

The Tools There are tools to unravel the conundrum.

(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

(c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

(e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;

(f) ... and

(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

⁴ S.84(1)

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.

⁵ It says that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation. -For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy” is not patentable. And the term “efficacy” was construed as “therapeutic efficacy” by Madras High Court on 6th August 2007. See <https://indiankanoon.org/doc/266062/>. This is accepted by the Supreme Court.

⁶ Supreme Court of India, Novartis Ag vs Union Of India & Ors. on 1 April 2013. See <https://indiankanoon.org/doc/165776436/>.

⁷ Song recorded by the Swedish pop group ABBA

Even in the text of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the social objectives like health needs and access to medicine are inbuilt. But however good a covenant or instrument may be, if those who are implementing it are not good, it will prove to be bad. However bad that covenant or statute may be, if those implementing it are good, it will prove to be good.⁸ And it is the wise judge who weighs in these objectives in the balance.

The United Nations Human Rights Council has confirmed the primacy of human rights, such as the right to health over trade, intellectual property rights and other bilateral investment or trade agreements. Resolution 32/L.23 reaffirms the importance of access to medicines for all human beings as one of the fundamental human rights and stresses that improved access could save millions of lives every year.⁹

The Constitution of every country contains implicitly or explicitly an assurance that there is a fundamental right to life. This must be expansively construed. "The right to life, we acknowledge, encompasses several rights ... each one of them being basic and fundamental. The(y) are the right to live with dignity, the right to shelter and the right to health. The State is obligated to ensure that these fundamental rights are not only protected but are enforced and made available to all citizens."¹⁰ How far can the Court stretch its arm to help? Rejecting the argument that courts can only issue declaratory orders, the South Africa Court said, "The nature of the right infringed and the nature of the infringement will provide guidance as to the appropriate relief in a particular case. Where necessary this may include both the issuing of a mandamus and the exercise of supervisory jurisdiction."¹¹

It is basic that the power to grant carries with it the power not to grant. But without going to that extreme, the judiciary has enough aids to facilitate access.

The Costa Rica-initiated COVID-19 Technology Access Pool (C-TAP) aims to make vaccines, tests, treatments and other health technologies to fight the virus accessible to all. This indicates the importance of access. If the vaccines and other health technologies are manufactured in developed countries, and made available only to the people there, and even within those countries, only to those groups who have access, it would be inviting disaster of a pandemic proportion.

The Nagoya Protocol can be used as a tool. What has been overlooked "...in the ongoing discussions on IP issues and Covid is that the Nagoya Protocol and its obligations require sharing of benefits arising from the use of genetic resources. Thus, any commercialisation of Covid-related treatment and/or prevention can be argued to be bound by this protocol and its benefit-sharing provisions."¹²

Resolution of the paradox. The judicial authority faced with balancing right to life against right to exclusivity and monetary gains has several tools to employ and to innovate solutions.

⁸ Echoing Dr. Ambedkar's final speech at the (Indian) Constituent Assembly on November 25, 1949: "However good a Constitution may be, if those who are implementing it are not good, it will prove to be bad. However bad a Constitution may be, if those implementing it are good, it will prove to be good."

⁹ Germán Velásquez, "Intellectual Property, Public Health and Access to Medicines in International Organizations", South Centre Research Paper 78 (July 2017).

¹⁰ Ashwani Kumar v. Union of India & Ors. With Sanjeeb Panigrahi v. Union of India & Ors.: 2019 Supreme Court.

¹¹ Minister of Health and Others v. Treatment Action Campaign and Others, available at 2002(5) SA 721.

¹² Balakrishna Pisupati, "Patent pooling, a Covid success story", *Hindu Business Line*, June 23, 2020.

It is clear that TRIPS had the pious intent of balancing public health. Even if it had got skewed midway, the course can be corrected now. There is sufficient compass guidance within TRIPS for the judicial authority to rule in favour of access.

It is undeniable that adequate access to affordable medicine or treatment to the stricken cannot be facilitated just by a judicial fiat. It needs executive will, and there are bilateral treaties and other tangential statutes that may come in the way of the TRIPS flexibilities having full play. The initiative and the incentive that a willing generic manufacturer can show is another issue. Even the generics, it is feared, may sing the same song. Sales of drugs "...will naturally be incentivized to focus on those who can pay more, rather than the vast masses who cannot afford much.... This not only unnecessarily raises prices, but reduces the possibility of weak patents being challenged."¹³ What effect will the present economic slow-down have on the generic manufacturers? This is, in the words of Prof. Shamnad Basheer "...a decision that calls into consideration issues of 'economic' and 'political' viability. In other words, the problem of 'access' moves beyond the realm of the purely 'legal' into the realms of 'economics' and 'politics'."¹⁴

The judicial authority will have to Choose Life. "Forced to choose between protecting the essential right to life - an unalienable right assured by the Constitution (Art.5) – or over ruling it in favour of secondary or financial interests of the State, I understand, as this dilemma is set out, that judicial ethics dictate to the judge only one possible option: to decide in favour of the undeniable right to life."¹⁵ While intellectual property right (IPR) has been termed as a human right, it is undeniably a granted right, and can be "ungranted". The right to life and the right of access to health is a far superior right. It is a right we are born with, like the right to dignity, and we cannot be disrobed of that right.

The time has come to innovate and find an alternative to the present patent system, one which does not rest solely on access-denying exclusivity, but one where innovation and access can co-exist. A monopoly today could literally kill millions. Commenting on the judgment of the Australia High Court in *D'Arcy vs. Myriad Genetics*, it is observed, "This judgment raises the question whether a patent regime should allow quality of life to be the commodity of a monopoly."¹⁶

Today that commodity will not be just the quality of life but the very continuance of life. The consequences of a pandemic cannot be geographically limited if supply of the cure is so limited. Even a superficial scan of the demography of the most vulnerable argues the case in favour of access. Therefore the South should present an alternative where both rights can be harmonised without jeopardising lives or diminishing the quality of lives.

This has happened earlier and the South has "resisted such corporate and political hegemony" that has "facilitated the capitalization of health in various forms", and has "been of vital importance and ha(s) won significant victories, but ha(s) not managed to transform or reverse the structural appropriation of health by capital."¹⁷ The judicial authority must infuse itself with a spirit of

¹³ Swaraj Paul Barooah, "Patents for Pharmaceutical Innovation – Basic Concerns", June 9, 2020. Available from <https://spicyip.com/2020/06/patents-for-pharma-basic-concerns.html>. The President Macron-Sanofi exchange is evidence of what is at stake.

¹⁴ Shamnad Basheer, "India's New Patent Regime: Aiding 'Access' or Abetting 'Genericide'?" (23 September 2007). Available from <https://www.ssrn.com/>. This was written 13 years ago, but is still relevant.

¹⁵ Passage from a Supremo Tribunal Federal (Brazil) judgment as quoted in *Patent and Trade Disparities in Developing Countries* by Prof. Srividhya Ragavan (OUP).

¹⁶ Lucas McCallum and Thomas Alured Faunce, "Myriad Voices Against Gene Patents in the High Court", (2015) *JLM* 23(2):322-9.

¹⁷ Kaushik Sunder Rajan, *Pharmocracy. Value, Politics and Knowledge in Global Biomedicine* (Duke University Press, 2017).

constitutionalism “that depends upon an interpretive, non-technocratic hermeneutics” and “has emerged as a democratic counter weight to logics of multinational pharmaceutical capital.”¹⁸ It shall weigh in the huge public interest factor when orders of injunction are sought for and cannot ignore it. There are dismal examples of when it should not have been granted.¹⁹ One might convincingly argue that a patent right is predominantly a “commercial” or market-oriented property interest and is therefore compensable in monetary terms.²⁰ And commercial interests can never take precedence over saving lives.

There is no acceptable data correlating the expenses incurred in inventing a drug and the price at which the drug is sold. The poser of whether there will be any invention without the rights being enforced and monetised is an arguable one. Assuming without conceding that it is so, it is possible to devise a different model of remuneration than the present one. The exclusive private ownership model lends itself to predatory tactics. Instead we may have other “innovative methods” like a patent pool working in cooperation with not just countries and international organisations but also the hundreds of researchers, innovators, companies and universities involved. This will help in combating the crisis and earning collectively.²¹ It may be time to think of a pervasive compensatory liability regime.²² It is not that this tension between the two rights has gone unnoticed. The Sub-Commission on the Promotion and Protection of Human Rights adopted Resolution 2000/7 on Intellectual Property Rights and Human Rights which has an antagonistic approach to TRIPS.²³

The relationship between the private rights and the public health rights should be spatially expanded in tune with the Constitutional aspirations rather than narrowly viewed as a private grasp of the patent owning few.²⁴ The Court shall explore the various models of rewarding or compensating the inventor, but the Court shall and is bound to defer to the always superior claim of the right to health over right to exclusivity. Today Hamlet’s question must be answered in favour of life.

¹⁸ Ibid.

¹⁹ In an order dated 12th June 2020, in *Pharmacyclics LLC vs Controller of Patents* in M.P.No.8/2020 OA/46/2020/PT/DEL the Intellectual Property Appellate Board (IPAB) in India resuscitated a revoked patent in respect of an anti-cancer drug Ibrutinib without any discussion of the public interest that was harmed and granted injunction pending the appeal against the revocation only because the Pharma company will suffer injury.

²⁰ Shamnad Basheer, “The End of Exclusivity: Towards a Compensatory (Patent) Commons”, *IDEA*, Vol. 58, No. 2 (2018), pp. 229-265.

²¹ Pratibha M. Singh, “Needed: a pandemic patent pool”, *The Hindu*, May 1, 2020.

²² Shamnad Basheer, “The End of Exclusivity: Towards a Compensatory (Patent) Commons”, *IDEA*, Vol. 58, No. 2 (2018), pp. 229-265. “Countries, particularly developing countries keen on retaining the space for technological imitation and growth ought to experiment more widely with compensatory liability frame, without fear of infringing TRIPS. In the ultimate analysis, a more pervasive compensatory liability regime takes us closer to the idea of a “compensatory innovations commons”.

²³ Laurence R. Helfer, “Human Rights and Intellectual Property: Conflict or Coexistence?” *Minnesota Intellectual Property Review* (2003). It stresses that “actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights. These conflicts cut across an exceptionally wide swath of legal terrain...”

²⁴ “From a patent law standpoint, it is rather difficult to discern what about the Supreme Court’s decision strikes the US Chamber of Commerce, Pfizer or Novartis as some great threat to innovation or the long-term welfare of patients. It may put a damper on the profits of Pfizer or Novartis as they are less able to extend the life of patents by minor modifications that result in patients and public health systems paying more for drugs. But, one should be very careful of confusing the interests of the shareholders of Pfizer and Novartis with the interest of patients in the United States, Europe, India or Kenya.” Frederick M. Abbott, “Inside Views: The Judgment In *Novartis v. India: What The Supreme Court Of India Said*”, 04/04/2013. Available from <http://www.ip-watch.org/>.

Author: Justice Prabha Sridevan served as Judge of the Madras High Court and Chair of the Intellectual Property Appellate Board of the Government of India. She is now retired.

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Email bernardo@southcentre.int, or telephone +41 22 791 80 50.**

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