PHARMACEUTICAL PATENTS AND THE COVID VACCINATION PATENT WAIVER

Deepti Taneja
Associate Professor
Department of Economics
Delhi College of Arts & Commerce
Joint Dean, Culture Council, University of Delhi
Email: dtaneja@dcac.du.ac.in

Abstract

The paper is aimed at analysing, historically and empirically, the importance of the use of pharmaceutical patents in promoting research and development and fostering innovation and inventions in the pharmaceutical sector. This debate became relevant in the wake of the covid 19 pandemic that was witnessed with peaks in 2020 and 2021 and the associated vaccine patent waiver that the World Trade Organisation undertook.

Section I gives a brief background on how the patents are the backbone of any pharmaceutical company as they provide the company the incentive to do Research and Development (R&D) activities for the production of new drugs. Section II traces the genesis of the patent regime in India and the provisions, especially with reference to the pharmaceutical sector, of the Indian Patents Act, 1970 and its amendments. Section III focuses on the covid vaccine patent waiver, first by presenting an overview of the vaccine status the world over and then a discussion of the genesis of the patent waiver argument along with the ensuing debate, with the social welfare vs the profitability argument discussed at length. Section IV provides the concluding notes of the waiver policy being finally adopted by the WTO in June 2022 and the reactions of the nations thereof.

Keywords: Covid, Pandemic, Patents, Pharmaceutical Sector, Vaccination, World Trade Organisation.

I. Introduction

The patents are the backbone of any pharmaceutical company. They provide the company the incentive to do Research and Development (R&D) activities for the production of new drugs. The research required

for producing the formula for any new drug involves huge cost outlays and by patenting these inventions, the drug companies ensure their profits by safeguarding themselves from their competitors manufacturing a similar drug. It is through patenting only that the costs spent on the R&D activities seem worthwhile to these pharma companies. There are some who argue that the R&D activities would be done anyway by these companies, which, without the profit motivation, seems a debatable argument in itself, especially in a market driven free economy (Yanni & Thomas, 2022). But even if one does give merit to such a school of thought, there is no denying the fact that such patents act as a catalyst for the drug companies to undertake these researches.

In a market driven free economy, especially in a high-cost industry like pharma, it is the profit earning motive that keeps the select firms alive and in business. Investment in the research for development of any new drug is akin to buying eggs in the hope of selling the chickens, albeit with some conditional probability. Not all eggs hatch, and even among those which do hatch, they do not give a homogeneous product to ensure uniform and high profitability. Similarly, investments in research of any new drug takes years and involve huge cost outlays and not all of these researches on new drugs culminate into patents for the same. Thus, without the motivation of profit, the companies would invariably shy away from making these investments (Jerry, 1994). By prohibiting their competitors from duplicating their drug formula, the patents act both as a cushion and an incentive to carry out these research activities that are necessary to develop and produce new drugs and formulas that have the potential to cure thousands of diseases and ensure a healthy survival of mankind and humanity at large.

II. Indian Patent Act, 1970 and its Amendments: Implications for the Pharma Industry

A Patent is a statutory right for an invention granted for a limited period of time to the patentee by the Government, in exchange of full disclosure of his invention for excluding others, from making, using, selling, importing the patented product or process for producing that product for those purposes without his consent (The Patents Act, 1970 and the Patents Rules, 2003). In the pharma industry, this ensures that the drug formula, using various components in prescribed ratios, is not duplicated by any other manufacturer.

The issue of patents rights in India is not a new one; such rights were introduced in India for the first time in 1856, called the Act VI of 1856. There were various amendments, addendums and deletions in the Act, till in 1970, The Patents Act, 1970 was passed, that repealed all other existing patent laws and acts in India. The Patents Act provides that any invention "that satisfies the criteria of newness, non-obviousness and usefulness" can be the subject matter of a patent (The Patents Act, 1970).

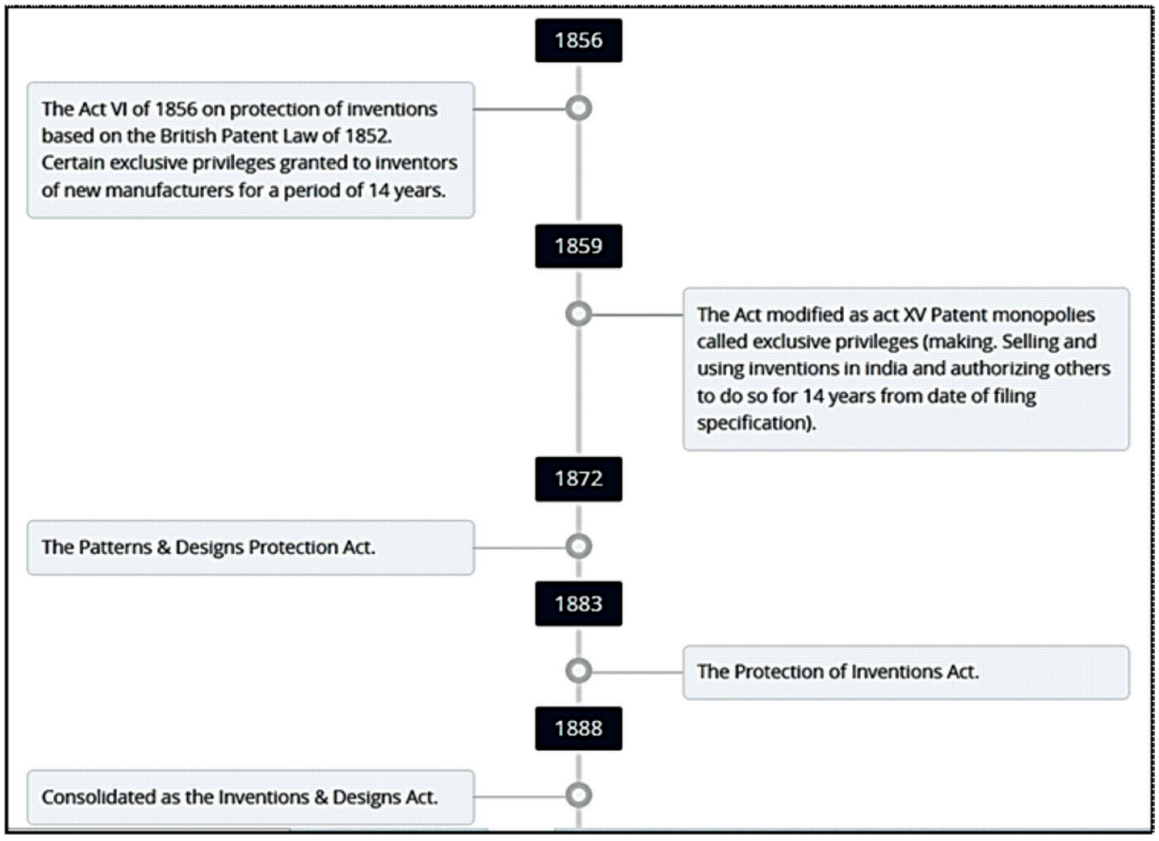
In the case of pharmaceuticals, the substances used in the drugs, that are, in themselves, capable of being used as food, stand-alone drugs or medicines, are not granted patents. It is when these substances are chemically processed, using a new formula, that leads to the formation of a new drug that has tested usefulness, that these drugs become eligible to be granted patents under The Patents Act, 1970. Thus, "methods of agriculture or horticulture, processes for the medicinal, surgical, curative, prophylactic or other treatment of human beings, animals or plants or substances obtained by a mere admixture, resulting only in the aggregation of the properties of the components, etc." are not patentable as per the provisions of the Act (The Patents Act, 1970).

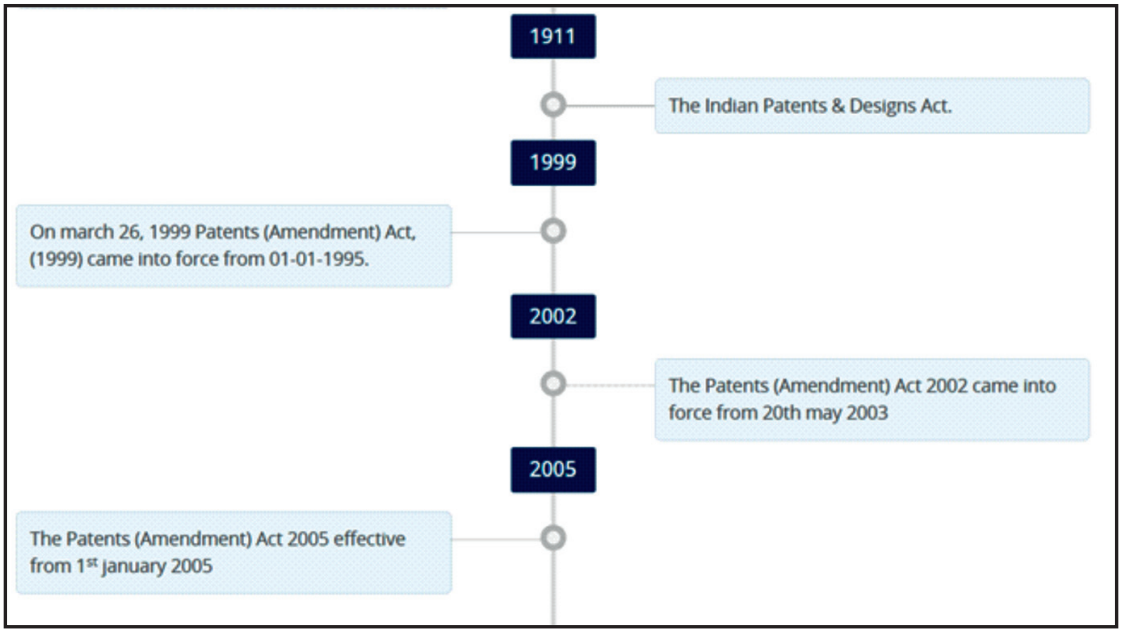
Having major implications in the pharmaceuticals industry, significant changes in the Indian Patents Act occurred after the formation of World Trade Organisation (WTO) when India signed the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement in 1995. Being a signatory to this Agreement, India was under obligation to make its Patents Act corroborate with the provisions of this agreement, and therefore brought about three major amendments in 1999, 2002 and the final one in 2005.

The Patents Amendment Act, 1999 was brought into force retrospectively from 1st January, 1995. The amended Act provided for "filing of applications for product patents in the areas of drugs, pharmaceuticals and agro chemicals, though such patents were not allowed." However, such applications were to be examined only from 2005 onwards and in the interim, the applicants could be allowed Exclusive Marketing Rights (EMR) to sell or distribute these products in India. The second most important amendment came about by way of The Patents Amendment Act, 2002, though this was implemented with effect from 20th May, 2003. This amendment provided for a uniform term of a patent for

a time period of 20 years, to be counted from the date of filing of patent application. This was a very important amendment as far as the pharma industry was concerned, having long term implications on the way drug trials are being held. The third amendment was introduced through the Patent Amendment Ordinance 2004 that came into effect from 1st January, 2005. This amendment provided patentability of pharmaceutical substances to the extent that patents would apply to new chemical entities. Section 3(d) of the Patents Act, 1970, explains that a new form of a known substance, new property / new use for a known substance and the mere use of a known process are not patentable and are not considered distinct from the known substance. Based on this principle, inventions using known substances were not to be henceforth patentable, unless the invention would have displayed "a significant increase in efficacy" (The Patents Act, 1970 and the Patents Rules, 2003). The last set of amendments in this Act were made in 2006 that were primarily to do with decentralised administrative facilitation and process-based mechanisms.

Exhibit 1: Diagrammatically shows the history of the Indian Patent System through the years





Source: Office of the Controller General Patents, Designs & Trade Marks, GoI website (https://ipindia.gov.in/)

One of the major fallouts of The Patents Amendment Act, 2002 is that the drug industry has fostered close associations with the medical institutions for their medical trials, as the drug companies have money and the resources to finance the drug trials, but they do not have the patients required for the same. Since usually the drug companies go in for the last stage of trials, i.e., the human trials, after they have obtained the patents, this directly eats into the time they have left of the patent period of 20 years to market and publicise their drugs. The human beings then become guinea pigs for these pharma companies, with complete understanding and tacit collusion of the medical practitioners. The long queues of 'medical representatives' of the big Pharma companies, waiting outside the clinics of popular doctors, is something that we all have witnessed and their motives, we are well aware of.

Delhi based independent civil society group All India Drug Action Network (AIDAN) in its study in 2019 (Rao, 2019) had claimed that illegal and unethical bounties, running into crores of rupees annually, are being offered to doctors under guise of consultancies, lectures and the like. Taking cognizance of many such prevailing practices, the Government of India has inserted Chapter III, Amendments to Direct Taxes, in the Finance Act of 2022, which states that "The legal position is clear that the claim of any expense incurred in providing various benefits in violation of the provisions of Indian Medical Council

(Professional Conduct, Etiquette and Ethics) Regulations, 2022, shall be inadmissible under section sub-section (1) of section 37 of Act being an expense prohibited by the law" (The Finance Act, 2022). In simple terms, this means that such an expenditure incurred by the Pharma companies cannot be claimed as a deduction for tax purposes, which will immediately lead to jacking up of the company's profits and thereby the payable taxes. This, it is hoped, shall have a dampening effect on such illegal and unethical practices being followed by the Pharma companies, in order to move around the provisions of the amendments of 2002 of the Patents Amendment Act.

A look at the Economic Survey of India's data (Economic Survey of India, GoI, 2021-22) with respect to the number of patents filed and granted in India will give a picture of the huge costs involved in the R&D process, yet resulting in less than half percentage of patents being granted.

Table 1: No. of Patents filed and granted in India between 2010-11 to 2020-21

Year	No. of Patents Filed	No. of Patents granted	% of patents granted vis-à-vis filed
2010-11	39400	7509	19.05%
2016-17	45444	9847	21.67%
2020-21	58502	28391	48.52%

Source: Author's own compilation using the Economic Survey of India 2021-22 data

Though this is a remarkable progress in recent years, the number of patents granted in India are still a fraction compared to patents granted in China, USA, Japan and Korea. According to World Intellectual Property Organisation (WIPO), the number of patents granted in China, USA, Japan and Korea stood at 5.3 lakhs, 3.52 lakhs, 1.79 lakhs and 1.35 lakhs, respectively for the year 2020 (Economic Survey of India 2021-22, Chapter 9). In the context of the Patent Act, it is noteworthy that a substantial amount of investment is done in R&D before the patents can be filed. Hence, less than half of the patent applications getting approval also have the direct implication on the profitability of the Pharma companies and the underlying pressure of making profits to sustain the organisation from among the drugs that actually make it to the market after the rigorous R&D and the patenting process. The

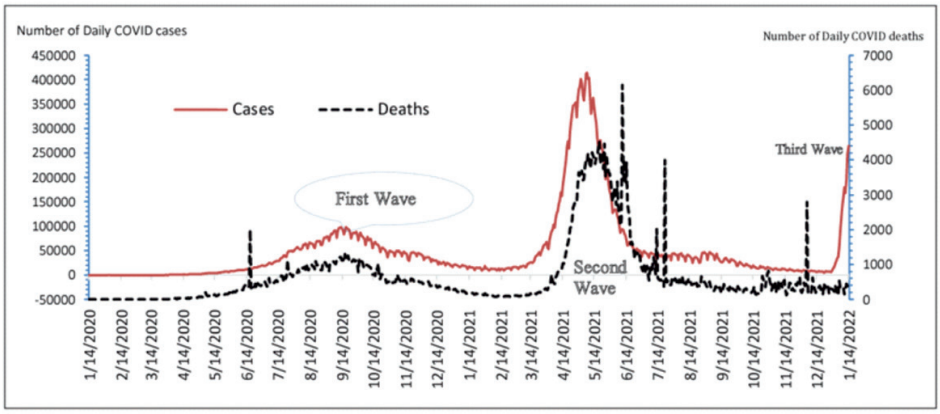
patents therefore do act as a cushion, crucial to Pharma companies' existence and profitability.

III. Covid Vaccine Patent Waiver

III.1 The Background: The extent of the disease and the vaccination status

Year 2019 saw the advent of the Covid-19, which was soon to take the world by storm in 2020 and this generation witnessed, what is being called by many, one of the world's worst pandemics ever. The covid-19 pandemic exposed the world over, all the vulnerabilities that existed in the social infrastructure, especially the health sector. Survival itself became a challenge and saving lives and livelihoods became mammoth tasks for governments the world over. Health response, especially of densely populated countries like India, became critical to controlling and mitigating the spread of the pandemic. Crucial to this was the development of covid-19 vaccines and their dissemination to the masses at highly subsidised rates or preferably, for free, by the governments, especially in thickly populated underdeveloped or developing nations.

Exhibit 2: Daily COVID-19 Cases and Deaths in India



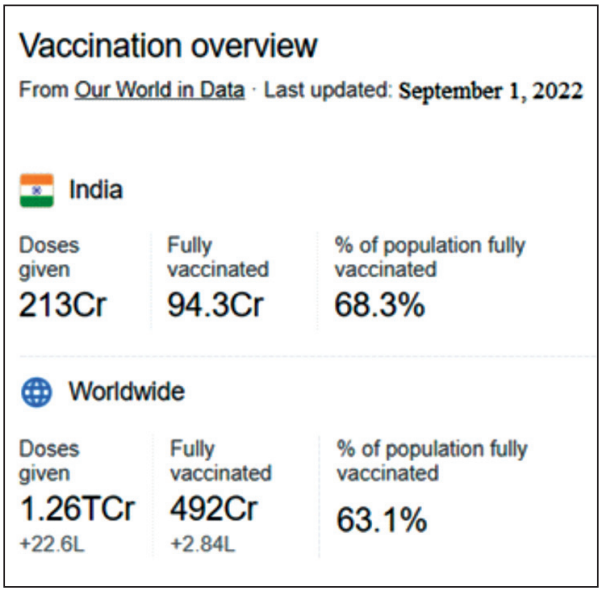
Source: World Health Organisation, as taken from Economic Survey 2021-22

Like the scenario was the world over, India too faced two massive waves of the pandemic, the second being deadlier than the first, both in terms of casualties and in terms of associated co-morbidities and impacts on peoples' health. Exhibit 2 shows the peak time of the two waves in India, in terms of surges in the number of daily deaths and cases. As per the Economic Survey of India 2021-22, during the first-wave, the cumulative number of COVID-19 cases started rising progressively from the month of May 2020, and peaked in mid-September 2020.

Thereafter, the country faced a massive surge in COVID-19 cases starting March 2021, with a peak of more than four lakh daily cases in May 2021 and more than 4400 daily deaths by the end of May 2021.

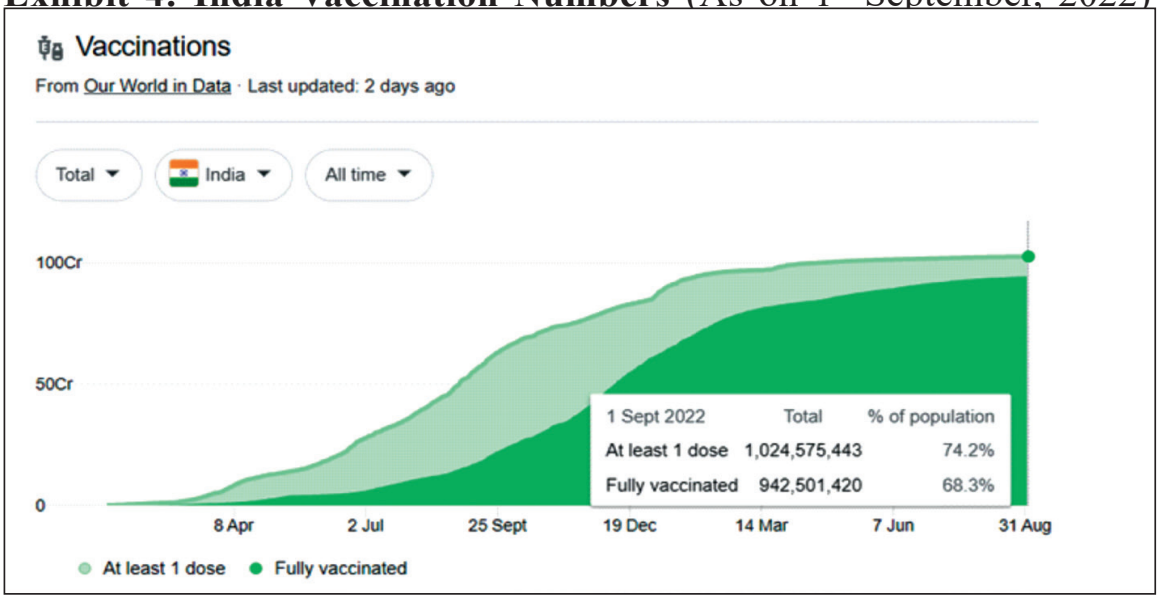
A fresh surge of cases and a new variant Omicron had surfaced in December 2021, but its effects were not felt as sharply as the first two waves, perhaps due to the vaccination drive launched by the country in its health response through the 'Aatma Nirbhar Bharat Abhiyan' packages and other related initiatives to mitigate the impacts of the pandemic. As on the date of writing this paper, i.e., till 1st September, 2022, 74.2% of India's eligible population had been administered at least 1 dose and 68.3% is fully vaccinated, which is higher than the 63.1% of the world eligible population figure. Exhibit 3 and 4 show the covid vaccination status in India and its overview.

Exhibit 3



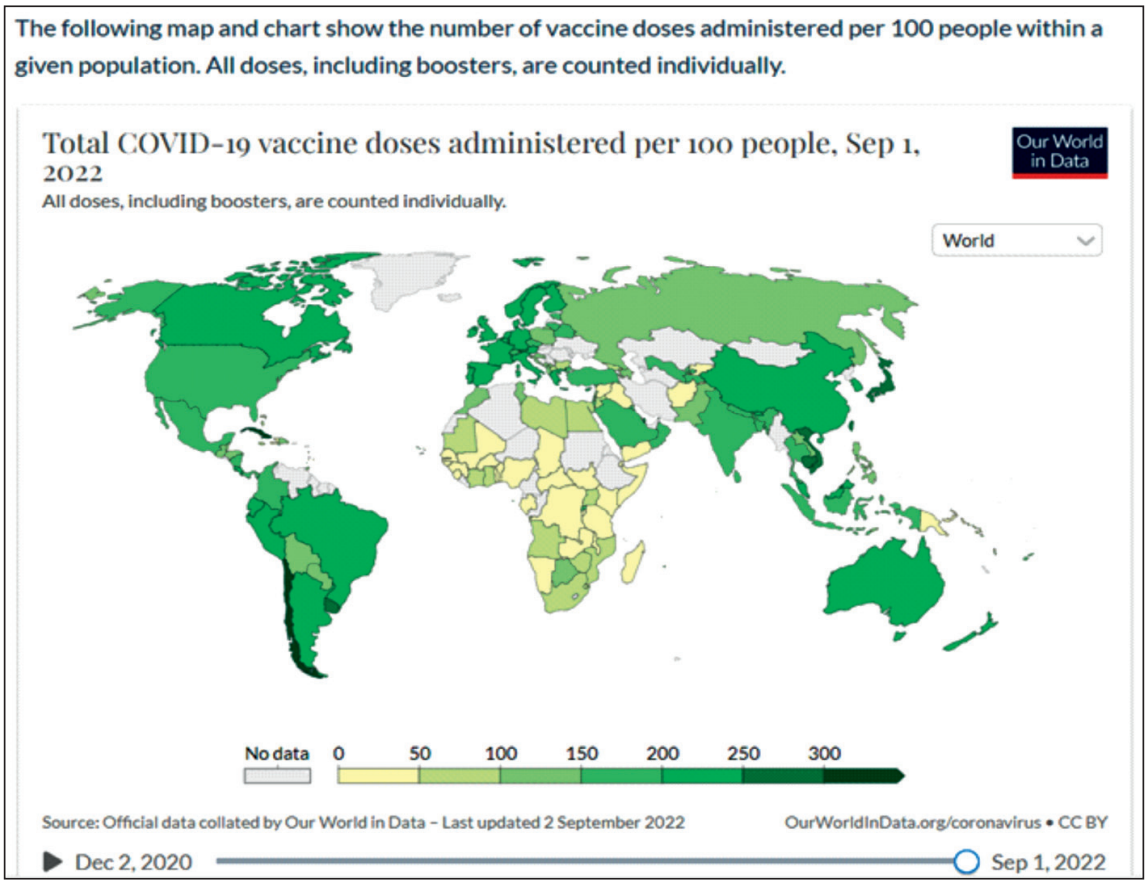
Source: "Our World in Data", Oxford Martin School, University of Oxford.

Exhibit 4: India Vaccination Numbers (As on 1st September, 2022)



Source: "Our World in Data", Oxford Martin School, University of Oxford

Exhibit 5

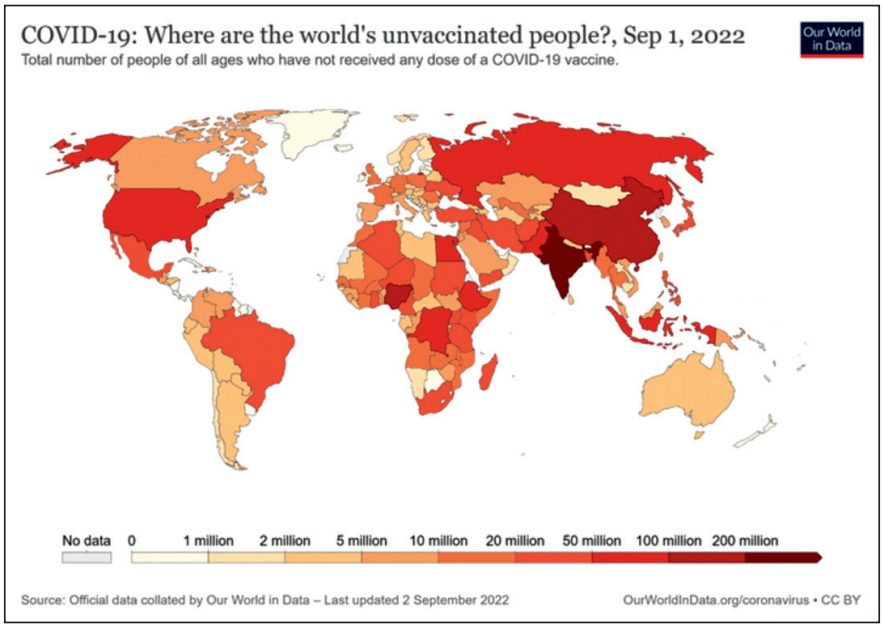


Source: "Our World in Data", Oxford Martin School, University of Oxford

India, despite being a thickly populated country, has so far fared well in terms of covid vaccine accessibility and administration. However, when one looks at the world comparative pictures regarding the covid vaccines administered and the number of people still not vaccinated across countries, we get the real picture of how mammoth a task this is, both for the covid vaccine manufacturers to keep up the supply and for the governments to administer these doses free.

The exhibit clearly depicts how almost all of the countries of the African continent have not even been able to vaccinate 50% of their population.

Exhibit 6



Source: "Our World in Data", Oxford Martin School, University of Oxford

These figures give us the real picture of where the world is in terms of covid vaccination. This brings to the fore the issue of accessibility and affordability by the nations, in the wake of the vaccines being patented, especially to those in Africa and other not so developed countries of the world.

III.2 The Genesis and the Debate: Issues of Covid Vaccine accessibility and affordability

After its initial outbreak in 2019 and the alarming heights it took in wake of the first wave in 2020, many activists, especially in the developing

world, dwelled on the contention that the World Trade Organisation's Intellectual Property Rights (IPR) regime limits access to vaccines by all, especially to those in the poor world. In the wake of the same, in late 2020, some countries, led by the initiative of India and South Africa, presented a proposal to the WTO to temporarily waive off the IPR protections, especially the patent-based protections for 'essentials', to combat the covid 19 pandemic. The waiver was demanded for pandemic-related health essential products and technologies, including vaccines, diagnostics, therapeutics, and personal protective equipment (PPE). WTO Director-General Ngozi Okonjo-Iweala had herself said in a public address that it was necessary to end the "morally unacceptable" inequity of access to Covid-19 vaccines. Pope Francis too had tweeted at that time that an equitable access to safe and effective vaccines should be fundamental to save lives and livelihoods and that Africa must not be left behind in providing access to covid vaccines, as according to him, no one was safe until everyone was safe.

This was, however, not for the first time that the WTO had been met with such a demand. Earlier too, for various life-saving drugs, especially for poor nations, it was demanded to have the patent protection waiver to ensure mass production of such drugs. Doha Ministerial Declaration of 14 November 2001, which came into effect from 2003, laid stress upon and provided validation for the use of 'compulsory licences' for the manufacture of such essential drugs and vaccines (The Doha Declaration, 2001, WTO). Under its provisions, the governments could issue compulsory licenses to allow other companies to make a patented product or use a patented process under licence without the consent of the patent owner, but only under certain conditions, aimed at safeguarding the interests of the patent holder. In essence, under a compulsory license, an individual or a company seeking to use another's intellectual property can do so without seeking the rights holder's consent, and pays the rights holder a set fee for the use of the specific license. However, for a pandemic of this proportion and magnitude, it was felt by the activists of public health that the compulsory licence route is too tedious, time consuming and piecemeal and would not have the desired result to increase the supply to meet the vaccine shortage that was felt in 2020.

The advocates of such a waiver felt that it would boost the production of the vaccines and, as a result of the same, the acute shortage that was

being experienced the world over could be eased. They also stressed that most of these pharma companies, including the big ones like Pfizer, BioNTech SE and Moderna, had been sponsored through generous government funding to support their research aimed at development of a safe and effective vaccine for covid, especially in a fast-paced manner. They advocated, that not only for the covid vaccination related research, but in general too, these pharma companies receive generous funds to undertake research from governments the world over and that over the past decade at least, their profits have always been on an upward trajectory. (Bill & Melinda Gates Foundation Report, 2020; Kansteiner, 2021 & Siripurapu, 2021)

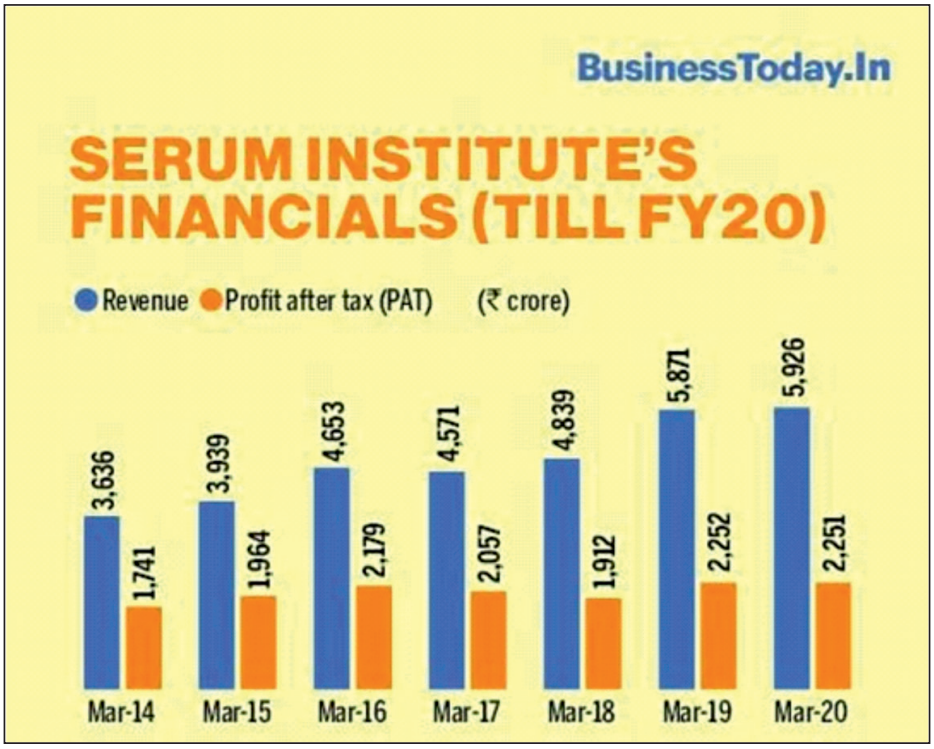
To get a deeper understanding of the profit positions of the big pharma companies in recent years and to get a picture of the steadily rising profits of various pharma companies the world over, a brief report of the case of Serum Institute of India (SII) has been analysed here in this paper. This profit-making pattern that has been observed in the case of SII, is similar to most of the big pharma companies of the world.

Pune based SII of India is the world's largest vaccine manufacturer and has recorded a surge rise in profits after the covid pandemic hit the world (Business Today Study Report, 2021). SII obtained the licence to manufacture and supply Oxford and AstraZeneca's vaccine, marketed with the brand name Covishield, and had received an overwhelming order for the production of the same.

Presented below in Exhibit 7 is a summary of SII's Financials, specifically the revenue and the Profit After Tax (PAT) values, till financial year 2020.

It is clear from Exhibit 7 that the company's income and net profit have been on the rise for a decade now. What is worth noting is that the company declared a growth of 158 per cent in disbursement in 2022, which stood at Rs 9,494 crore (SII statistics, 2022). A look at the growth figures of all major pharma companies of the world reveals similar patterns.

Exhibit 7



Source: Study by the Business Today group, sourcing from 'Prowess IQ'

On the other hand, those opposing this move of patent waiver, argued that it is not the patent, but the low manufacturing capacity and the distributional bottlenecks that create the problem of accessibility of essential drugs in some countries. They felt that such a move will provide a disincentive to many pharma companies to henceforth invest in breakthrough medicinal research and those at the final stages of trials of covid vaccines too would feel the heat of such a waiver. They also stressed that the route of compulsory licence was always available to the governments that actually felt that there was a manufacturing shortfall for such drugs or vaccines.

They further argued that it was not the patent protection that had led to the vaccine shortfall in 2020-21, but the access to critical ingredients that was in short supply. It was also stressed that without the technical know-how and the expertise to produce such vaccines, a mere patent protection waiver would not really boost the manufacturing in the countries that were supporting such a move. Some even argued and criticised the USA for hoarding these vaccines, which they felt, was one of the primary reasons for geographical inequality in vaccine access.

III.3 Covid Vaccine Patent Waiver Granted: Provisions and Possible Implications

After a two year long effort, in June 2022, the WTO did grant a patent waiver for covid vaccine manufacturing. However, India and the other countries that had led this move, call this stance half-baked and too late. It was felt that the negotiations at WTO took too long and it was only a timely intervention that could have prevented mass scale covid deaths, especially in the peak of the second wave. Presently, it was felt the world over, that there is no supply side constraint on the availability of the covid vaccines. The same is evident as per the data released by the European Federation of Pharmaceutical Industries and Associations, that, as of May 2022, there were 2.1 billion excess doses of Covid-19 vaccines and their production had outpaced the number of doses administered in recent months (European Council Reports and Publications, 2022).

It was also felt that since this five-year waiver was limited only to COVID vaccines and exempted the treatments for those with the virus, such as antibodies and antivirals, as well as the covid testing kits, the pressing issue and need of the hour had again been side-lined and this patent waiver was more like a paper tiger and a political gimmick. India's Commerce and Industry minister Piyush Goyal was quoted as reporting in mid-June 2022 that "only 14 percent of people in low-income countries have been vaccinated with one dose, while in November last year, the People's Vaccine Alliance reported that Pfizer, BioNTech and Moderna, the companies behind two of the most successful COVID-19 vaccines, were together making $65,000 every minute. In another distressing fact, pharma giants like Pfizer and BioNTech had delivered less than 1 per cent of their total vaccine supplies to low-income countries, while Moderna had delivered barely 0.2 per cent." (Goyal at WTO Ministerial Meet, June 2022)

IV. Conclusion

Patents indeed are the backbone for any industry, especially more so for the pharmaceutical companies, as the R&D for their products are both extremely costly as well as time consuming. However, despite this, there is no denial to the fact too that the pharma companies do find ways to ensure profitability of the company and have in the past managed to manoeuvre around deftly some of the clauses of various Acts, including the Patent Act, 1970 and its amendments.

A policy like patent waiver is indeed a tightrope walking, where all sides of the argument seem meritorious. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) had pointed to other "real challenges" that exist in scaling up production and distribution of Covid-19 vaccines. These include trade barriers, bottlenecks in supply chains, scarcity of raw materials and ingredients in the supply chain, and the unwillingness of rich countries to share doses with poorer nations. The scarcity of raw materials has been a growing issue for ramping up production; several manufacturers have been relying on specific suppliers, and alternatives are limited. Also, countries like the US had blocked exports of critical raw materials used in the production of some Covid-19 vaccines using regulations like the American Defence Production Act.

The present covid 19 wave seems to have been tided over and so does it seem that the vaccine shortage problem has been addressed too quite effectively in the present time. However, should such a health issue of this mammoth scale and intensity arise again in near future, the critical question remains whether patent waivers can resolve the issue of vaccine shortages. This is a complex question to which there is, so far, no clear answer. Besides merely patent issues, there are other considerations associated with vaccine manufacturing. Technology transfer is integral for commencing production. For instance, Pfizer had pointed out that its vaccine requires the use of 280 components from 86 suppliers and highly specialised manufacturing equipment. There is also the principle of scale operations that point out that it takes a considerable amount of time, even several years, for any producers' plants to become operational at optimal capacity. This raises the question of whether today's vaccines would even be relevant at that point in time, especially if new variants prove resistant to vaccine formulations currently available. Furthermore, in parallel to the waivers, a transfer of personnel, raw materials and equipment to developing nations also becomes necessary with such a waiver. This will involve waiver or total relaxations in various WTO agreements and treaties, which, if ever undertaken, shall open another Pandora's Box of its own. The question of equity versus profitability has always been merit driven upon individual cases and circumstances and the same holds true for drug patent waivers too. One can however conclude that the covid patent waiver, though too late and too little, has at least paved the way for future negotiations on the matter on similar lines, should the need arise.

Author Bionote**:** *Dr. Deepti Taneja is Joint Dean, Culture Council, University of Delhi and an Associate Professor of Economics at Delhi College of Arts and Commerce, University of Delhi. She is an Associate Editor of the Indian Economic Journals Special Issues and is also Managing Editor of the Bihar Economic Journal. She is also the Public Information Officer and Joint Secretary of the Indian Economic Association and a member of the Academic Council, Sushant University, Gurugram. As recognition of her outstanding contribution to the aim of teaching, Dr. Taneja has been conferred with various awards from government and non-governmental organizations.*

References

Acharya, R. (2008). *The Global Significance of India's Pharmaceutical Patent Laws.* American Intellectual Property Law Association.

Annual Report (2020-1, 2021-2). Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

Bill & Melinda Gates Foundation Report. (November 2020). *Gates Foundation announces new funds to develop COVID-19 vaccines and increase access to affordable vaccines in low-income countries.*

Bulow, J. (2004). *The Gaming of Pharmaceutical Patents*. Innovation Policy and the Economy, University of Chicago Press Journals, 4, 145-187.

Business Today Study Report. (May 2021). *How profitable is Adar Poonawalla's Serum Institute?*

Conoway, C. (2003). *The Pros and Cons of Pharmaceutical Patents.* Regional Review, 13 (1).

Davis, W. (July 16, 2001). *When Patents Expire*. Brandweek.

Doha Declaration (2021). Doha Development Agenda, World Development Organisation.

Economic Survey of India (2021-2). Government of India, January 2022.

Research and Publications (2022). European Council, Council of the European Unio.

Field, A. (November 2003). *Gaming of Pharmaceutical Patents*. Stanford Business Magazine.

Flint, J. (September 5, 1994). *The Goose that Laid the Golden Pill*. Forbes, 153(10).

Hoen, E. (2002). *Pharmaceuticals: Patents, Prices and Patients.* Chicago Journal of International Law*,* 3.

Hoffman, J., Shah, N., Vermeulen, L., Shumock, G., Grim, P., Hunkler, R. & Hontz, K. (2007). *Projecting future drug expenditures.* American Society of Health-System Pharmacists, 64, 298-314.

https://ipindia.gov.in/

https://ourworldindata.org/

Kamal, Y.M. & Cueni, T. (March 2022). *Should covid-19 vaccines and drugs be "not for profit"?* BMJ Clinical Research Journal

Kansteiner, F. (April 2021). *Bharat Biotech, government cash and partners in hand, aims for 700M COVID-19 shots per year.* Fierce Pharma Report

Mirza, Z. (1999). *WTO/TRIPs, Pharmaceuticals and Health: Impacts and strategies, The Society for International Development.* SAGE Publications.

Rao, A.M. (2019). All India Drug Action Network, Working Paper 3.

Siripurapu, A. (2021). *The Debate Over a Patent Waiver for COVID-19 Vaccines: What to Know.* Council on Foreign Relations.

The Finance Bill. (2022). [As introduced in Lok Sabha—Bill no. 18 of 2022]

The Finance Act. (2022), Ministry of Law & Justice, Government of India. [No. 6 of 2022]

The Indian Patent Act. (1970). Intellectual Property India, Govt. of India

The Patent Rules. (2003). Intellectual Property India, Govt. of India

World Trade Organisation News. (2003). *Decision removes final patent obstacle to cheap drug imports*. Press/350/Rev.1.

Zacharias, N. & Farias, S. (November 2019). *India: Patents and the Indian Pharmaceutical Industry.* Mondaq.com.