PUBLIC FUNDED RESEARCH, PATENTS AND PHARMACEUTICALS

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Abstract

The concept of patenting pharmaceutical innovations has been always a point of debate in the academic community. There is some consensus of opinion that lifesaving drugs are often not affordable to the public because of the patents on such drugs. The recent Covid-19 pandemic have sparked the debate further especially in reference with vaccine equity and access. Further, studies also showed that 97% of Oxford AstraZeneca Covid vaccination was public funded, yet it was provided to public at huge prices. This along with other empirical studies which provided evidence that majority of the pharmaceutical products are being made in the public funded research institutions first and then commercialised to private industries, also shifted the focus of such debates. This Article tries to gather evidence on to what extent the pharmaceutical products are being made in the public funded institutions. After finding substantial evidence to indicate that the majority of the pharmaceutical products had their origins in pubic funded research, the article attempts to address the issue whether it is equitable for the public to not have access to such products created using public funds. The article examines the role of Government and public funded research institutions in ensuring access to pharmaceutical products created using public funds.

Keywords: Pharmaceutical products, pharmaceutical patents, public funded research, equitable access, pandemic.

1. Introduction

Patenting of pharmaceutical products has always been a point of debate in the academic community. On the one hand there exists the concern that patents deter access to lifesaving medicines and on the other hand patents are seen as an essential incentive for investing in the development of new innovative pharmaceutical products and devices. While the literature on the need and consequences of patenting pharmaceutical products

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are divided in opinion, there is a common consensus that the laws and policies for patenting pharmaceutical products should always try to achieve a trade-off between the invention and access. However, this intrinsic debate on how to effectively use patents for incentive and how to ensure access have caught new momentum in the wave of the Covid pandemic.

This increased attention to the problem of 'access' to patented pharmaceuticals have given rise to a new strand of both academic and legislative initiatives which have emphasised the potential role the public funded research institutions could play in shrinking the gap between the pharmaceutical products and the public. Such initiatives are based on the idea that most of the inventions that are taking place in the pharmaceutical industries all over the world had its origins in public funded university or research institutions patents. There is also evidence to indicate that such universities and research institutions are also the leading patent holders in medicinal drugs and devices in many countries. This article attempts to gather the evidence on these university-owned pharmaceutical patents and determine the role of the public funded institutions to increase access to the pharmaceutical products.

2. Evolution of the Concept of Patenting Public Funded Pharmaceutical Inventions

Traditionally, the outputs of academic research have always been placed freely in the public domain, to be picked up either by fellow and future researchers for further pursuit of knowledge or by entrepreneurs for industrial or commercial application of the knowledge created in public institutions. Intellectual Property Rights related concerns did not bother public funded institutions for a long time. Dedicating research outputs to the public domain for free use and follow-on research was the standard practice in public-funded research. However, after World-war II, while countries all over the world were trying to recover from the economic injuries the war left on them, the onus was placed on the public funded research institutions and universities to help them recover faster. This was especially more so in the US, where the research universities and institutions were expected to contribute more directly to the economy. There was growing concern about the apparent decline in the social value of public research in the US as the inventions resulting from public-funded research were not reaching the market place.

Lack of IPR policies and legislations were said to be the main reason behind the lack of access to public funded inventions. Most inventions that are taking place in the research institutions may most often be in their 'embryonic' form, requiring additional investments for developing them into usable products, even if the inventions are in their final prototype stage of development, additional investments are needed for mass production, distributions and clinical trials. Most research institutions lack the skills or authority to develop their inventions to the point where they can be commercially made available to the public. Hence, such university inventions must be transferred to industries so that they can take up the further development and commercial development of the product. However, it is believed that the private industries lack incentive to invest huge amounts into the commercial development of university inventions without some proprietary rights. Hence, patents are granted to universities and research institutions which then licence or assign their ownership in such inventions to the industries for commercialisation of research results.[1]

This prompted policy-makers to enact new legislations to promote patenting, technology transfer and industrial application of inventions generated from publicly funded research. Two consecutive legislations were passed in the US in the year 1980 with this vision. The first one, *the Stevenson-Wydler Technology Innovation Act of 1980*, made technology transfer an integral part of the research and development responsibilities of federal laboratories and their employees.[2] The second statute was *the University and Small Business Patent Procedures Act (1980)*, commonly known as the Bayh-Dole Act. The Bayh–Dole Act gave the research institutions and universities the right to choose ownership over their inventions and to file for and retain patent rights.[3] The Act also gave the right to licence these patented inventions to the industries on an exclusive or non-exclusive basis.[4]

After the enactment of the Bayh-Dole Act, the patenting and licensing activities of the US research institutions grew dramatically and literature shows that most of this

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1 K A. Lemley, "Are Universities Patent Trolls?" 18 *Fordham Intellectual Property, Media & Entertainment Law Journal* 615 (2008); Arti Kaur Rai, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science" 94 *Northwestern University Law Review* 87 (1999).

2 United States Code, Title 35 – PATENTS.

3 *Ibid.*

4 *Id.* at 2.

growth was concentrated in the biotechnology and pharmaceutical sectors.[5] However, this growth in patenting and licensing numbers were not received positively by the academicians and in fact literature shows that the negative outcomes of patenting and licensing public funded pharmaceutical inventions far outweighs the positive outcomes. While the positive outcomes of patenting and licensing pharmaceutical inventions were one, it led to a dramatic increase in the private sector investment in R&D of pharmaceutical products. Several medicines, medicinal devices and pharmaceutical industries were made because of this patenting of pharmaceutical products. However, there were several concerns associated with aggressive patenting. One, it shifted the focus of academic research from basic towards more 'applied' research on pharmaceutical inventions that had a market, for example, cure for life style diseases and the research on diseases, especially the ones affecting the developing countries remain neglected.[6] Two, excessive patenting led to include more research tools in the patenting realm and this created hindrance to further research.[7] Three, the aggressive patenting also led to a decreased quality in the patents granted, creating patent hold-ups and a patent 'anti-commons'.[8] Four, it led to a decrease in the other modes of technology transfer through which information dissemination took place without proprietary rights, mainly the publications of research results.[9]

The last and the most important, the main rationale for patenting public funded inventions, i.e. to ensure access by the public, was not happening. Studies actually show that while the patenting of pharmaceutical inventions increased, it did not result in the corresponding increase of licensing of patented products.[10] Further, even when the

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5 Pierre Azoulay, Ryan Michigan, *et.al*., "The Anatomy of Medical School Patenting" 357 *New England Journal of Medicine* 2052 (2009).

6 Jean O Lanjouw and Margaret MacLeod, "Pharmaceutical R&D for Low-Income Countries: Global Trends and Participation by Indian Firms" 39 *Economic and Political Weekly* 4237 (2005).

7 David C. Mowery, Richard R. Nelson, *et.al*., *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and after the Bayh-Dole Act* 1 (Stanford University Press, Stanford, 2004).

8 Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" 280 *SCIENCE* 698 (1998); Anthony D.So, Bhaven N. Sampat, *et.al*., "Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience" *Intellectual Property Rights: Legal and Economic Challenges for Development* 209 (2014).

9 Jerry G. Thursby and Marie C. Thursby, "Has the Bayh-Dole Act compromised Basic Research?" 40 *Research Policy* 1079 (2011).

10 David C. Mowery and Bhaven N. Sampat, "The Bayh-Dole Act of 1980 And University–Industry Technology Transfer: A Model for Other OECD Governments?" 30 *The Journal of Technology Transfer* 122 (2004).

patented products were licensed, the cost of such products was so high that the average general public did not have access to it.

3. The Role of Public Funded Research Institutions in Ensuring Access to Pharmaceutical Products

To identify the role of public funded research in the pharmaceutical industry one has to first determine the problems faced by the public in accessing these inventions and the level of patenting activities in the public funded research institutions in the pharmaceutical sector. The literature shows that major discoveries in the pharmaceutical field that provided a treatment method for many diseases originated in the public funded institutions. These drugs were commercialised to the private industries for its exploitation. However, the private industries charged insanely huge amounts of price for these drugs which were made using the taxpayers' money making them unaffordable to the larger public. Another area of concern is the problem of follow-on patents and evergreen patenting by private industries from public funded patents or licences. Literature shows that often private industries have two or more follow-on patents on drugs created using public funded research results without any significant innovation citing new formulation of new indications.[11]

However, there is currently a scarcity of exact empirical data on how much of the pharmaceutical patents are owned by public funded institutions. However, there have been some attempts all over the world to quantify the data on pharmaceutical patents held by public funded research institutions, yet the bulk of this data is concentrated in the US and hence this article only looks into the US experience.

According to a UN Report, most drugs currently in the market in Europe, North America, and Japan, have been made in public funded research institutions, which further licence these drugs to the industries for its commercial exploitation. In another study, it was found that around 70% of new drugs with therapeutic advances in the US were created using public funds.[12] It was further found that, the funding from the National

[11] Lisa Larrimore Ouellette, "How Many Patents does it take to make a Drug-Follow-On Pharmaceutical Patents and University Licensing" 17 *Mich. Telecomm. & Tech. L. Rev.* 299 (2010); Hemphill, C. S., & Sampat, B. N., "Evergreening, Patent Challenges and Effective Market Life in Pharmaceuticals" 31 *Journal of Health Economics* 331 (2012).

[12] United Nations Development Programme, Human Development Report, *Globalisation with a Human Face* 1999.

Institutes of Health (NIH) have played the major role in the creation and to the overall growth of the private sector pharmaceutical industries in the US, by licensing or assigning patented products created using their funds to the industries.[13] Basic research that led to major drug discoveries for diseases like tuberculosis,[14] other infectious diseases,[15] and cancer was mostly public funded. The public funded research in the genome area has also given rise to the development of many drugs.[16]

In another study it was found that the pharmaceutical giant Novartis was the major player that mostly made use of the patented public funded inventions.[17] For instance, Novartis used several patents and licences from public funded research to develop the revolutionary drug, Gleevec for the treatment of chronic myelogenous leukaemia, which was then marketed at huge prices.[18] Recent insights also indicate that one of the world's most costly drug, Zolegensma used for the treatment of Spinal Muscular Atrophy in young children under two years have been created using patents from University of Pennsylvania[19] and Nationwide Children's Hospital.[20] Further, several charities both in Europe and US alike have contributed to the development of these drugs.[21] Additionally, most of the pre-clinical trials that led to the FDA approval of the drug, Zolgensma, were also done in Nationwide Children's Hospital and the Ohio State

[13] Ekaterina G. Cleary, Jennifer M. Beierlein, *et.al.*, "Contribution of NIH Funding to New Drug Approvals 2010–2016", 115(10) *Proceedings of the National Academy of Sciences* 2329 (2018).

[14] Christian Lienhardt, Mario Raviglione, *et.al.*, "New Drugs for the Treatment of Tuberculosis: Needs, Challenges, Promise and Prospects for the Future" 205 (Suppl 2) *Journal of Infectious Diseases* 243 (2012).

[15] Carolyn K. Shore and Allan Coukell, "Roadmap for Antibiotic Discovery" 1(6) *Nature Microbiology* 1 (2016).

[16] Rebecca S. Eisenberg, "Patents and Data-Sharing in Public Science" 15(6) *Industrial and Corporate Change* 1023 (2006).

[17] Kunmeng Liu, Zixuan Gu, *et.al.*, "Global Landscape of Patents Related to Human Coronaviruses" 17 *International Journal of Biological Sciences* 1588 (2021).

[18] Jessica Wapner, *The Philadelphia Chromosome: A Mutant Gene and the Quest to Cure Cancer at the Genetic Level* (The Experiment, 2013).

[19] Press Release of Penn Medicine, May 24, 2019, *available at*: https://www.pennmedicine.org/news/news-releases/2019/may/zolgensma-based-on-delivery-system-discovered-by-penn-gene-therapy-pioneer (last visited on November 28, 2022).

[20] Press Release of Nationwide Children's Hospital, October 18, 2013, *available at*: https://www.nationwidechildrens.org/newsroom/news-releases/2013/10/avexis-biolife-licenses-spinal-muscular-atrophy-sma-patent-portfolio-from-nationwide-childrens (last visited on 28 November 2022) AveXis was later bought by Novartis

[21] Press Release of Sophia's Cure Foundation, September 8, 2010, *available at*: http://www.sophiascure.org/sma-research/spinal-muscular-atrophy-research-team-receives-pepsi-refresh-funds-from-sophias-cure-foundation (last visited on November 28, 2022).

University College of Medicine.[22] It is appalling to note that a drug developed substantially using public funds and charity is priced at $2.1 million per dose, a price even the billionaires may not be able to afford.

Another area where private industries are reaping profits at the expense of public health are from the drugs and treatments for HIV/AIDS people killing diseases. Studies show that, most of the treatment methods for HIV/AIDS have also been discovered in the public funded institutions. In one study, it was found that the universities owned major patents on over one fourth of the HIV/AIDS drugs approved since 1988.[23] The treatment using 'Antiretroviral' for HIV/AIDS, was also done in a public funded research university.[24] One major drug 'Stavudine' created in Yale University was sold at such high prices that several criticisms and protests arose for charging such high prices for a public funded drug for the most cataclysmic disease in the developing world, especially in South Africa. As a consequence the Yale university intervened and stressed the licences of the patent, Bristol-Myers Squibb, to not to enforce the patent in South Africa.[25] It was revealed that this involvement by the University led to a "30-fold reduction in the drug's price and a dramatic expansion of HIV treatment programs in South Africa."[26]

Further, the post-pandemic efforts on ensuring vaccination equity and availability have also led to multiple studies being done on the relationship between treatment for Coronaviruses and Public funded research. In a study, it was found that the most number of patents related to the Coronavirus were owned by the Government owned or public funded institutions.[27] In another study it was found that the Oxford/AstraZeneca Covid-19 vaccine was 97% public funded.[28]It may also be possible that vaccines of Moderna and Pfitzer are also substantially public funded, however since there is no

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22 Press Release Nationwide Children's Hospital, May 24, 2019, *available at*: https://www.nationwidechildrens.org/newsroom/news-releases/2019/05/zolgensma-fda-approval (last visited on November 28, 2022)

23 Bhaven N. Sampat, "Academic Patents and Access to Medicines in Developing Countries", 99(1) *American Journal of Public Health* 12 (2009).

24 *Ibid*.

25 Daryl Lindsey, ''Amy and Goliath,'' *Salon* 2001, *available at*: http://archive.salon.com/ news/feature/2001/05/01/aids (last visited on November 28, 2022).

26 Dave A. Chokshi, "Improving Access to Medicines in Poor Countries: The Role of Universities", 3(6) *PLoS Medicine* 136 (2006).

27 Kunmeng Liu, Zixuan Gu, *et.al.*, "Global Landscape of Patents Related to Human Coronaviruses", 17(6) *International Journal of Biological Sciences* 1588 (2021).

28 Samuel Cross, Rho Yeanuk, *et.al.*, "Who funded the research behind the Oxford–AstraZeneca COVID-19 vaccine?", 12 *BMJ Global Health* (2021).

extensive study one cannot possibly come to the conclusion.[29]The shortage and affordability of vaccines have been criticised heavily by various scholars, governments and the public.

As was seen in the above section, many of the lifesaving medicines are wholly or partly developed using public funds, which leads to certain questions, as to, who decides the price of inventions that are being made primarily using taxpayers' money; why are the governments and Public funded institutions not intervening even with such huge public uproars over the availability and affordability of life saving drugs and treatments; why does the public have no access to life-saving drugs despite contributing financially for the development of the same, and so on. The Government and public funded institutions have a huge responsibility to make life-saving drugs more accessible by re-defining their research priorities and patenting and licensing decisions, so in this regard what does the law have to say about it?

4. Legislative and Policy Framework for Ensuring Access to Public Funded Pharmaceutical Inventions

While the Bayh-Dole Act was passed in the US to facilitate the patenting and licensing of public funded inventions, it also had several provisions to ensure that the public had access to such inventions. First, the Act requires any potential licensee to provide a plan for the development or marketing of the invention and the institutions have to make sure that the plans and abilities of the potential licensee can actually promote the utilization of the invention by the public. Further, even though the Act provides for both exclusive or non-exclusive license, it stipulates that exclusive licences may only be provided under the Act, if the public utilization of any invention could not be achieved or achieved expeditiously by non-exclusive licenses or if exclusive licensing is the only way to recoup the high risk investments that has to made to bring the invention to practical application or otherwise promote the invention's utilization by the public. The Act further calls for a preference to the US industries; i.e. exclusive licenses can only be given if the licensee agrees that the invention shall be manufactured substantially in the US.[30] Also, while granting exclusive or partially exclusive licenses, public notice has to be given

[29] "U.S Reverses Stance, Backs Giving Poorer Countries Access to COVID Vaccine Patents", *Reuters* May 5 2021, *available at*: https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/ (last visited on November 28, 2022).

[30] United States Code, Title 35, $204.

about the same and opportunity to file objections must be provided. Such a provision is incorporated to make sure that the interests of the Federal Government and the public will best be served by the proposed license. Further, the institution shall not grant an exclusive license, if the grant of such license will substantially tend to lessen competition or result in undue concentration or results in any other situations inconsistent with the antitrust laws. Further the act states that in granting a license to use the invention, the University also generally must give priority to small businesses, if they are equally capable of bringing the invention to practical application like other firms which are not small business firms.

The Bayh Dole Act also has a so called 'March-in provisions', which enables the Federal Government to require the universities to license the inventions to other parties, if the licensee, has not taken effective steps to achieve practical application of the subject invention in a reasonable time or if such other licenses are necessary to alleviate health or safety needs to meet requirements for public use which are not reasonably satisfied by the current licensee.[31]

Thus it can be seen that in the US the law clearly gives the Government the right to review the prices of pharmaceutical products developed using public funds. If the public cannot afford the medicines at a reasonable price, the government can take away the licence or give licence to other industries or amend the licensing terms so as to include reasonable pricing of the products. Yet after four decades of passing the Act, and even after numerous public pressures and direct petitions to the National Institutes of Health, the Government has still not enforced the 'March-in Rights' in the US.[32]

Coming to the Indian scenario, we do not have a Bayh-Dole like legislation in India. However, a Public Funded IP Bill was introduced in 2008; however it was not passed into law owing to the large criticisms it received since its introduction.[33] The Indian Public Funded IP Bill had almost similar provisions with that of the US Bayh Dole Act. Even though the Indian Bill resembled the Bayh Dole in its basic structure, a

[31] United States Code, Title 35, $203.

[32] Peter S. Arno and Michael H. Davis, "Why Don't We Enforce Existing Drug Price Controls - The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research", 75(3) *Tulane Law Review* 631 (2000).

[33] K. Satyanarayana, "The Indian Public Funded IP Bill: Are We Ready?", 128(6) *Indian Journal of Medical Research* 682 (2008).

comparative read-through of the provisions of both instruments reveals some thought-provoking and even appalling deviations. For example, as stated above, the US Act contains various provisions designed to regulate the licensing inventions and to step in if benefits are not made available to the public on reasonable terms. However, the Indian Bill contained no such terms and conditions. Unlike its US counterpart, there were no requirements in the bill as to how the commercialization of research results is to be undertaken. There were no provisions to address the issues of how access and benefit to the public will be ensured. There were also no provisions for intrinsic march in-rights in the bill, which raises the question as to whether the bill will in fact achieve the sought objective of making the research results available to the public. The lawmakers did an important oversight in this process of drafting the bill. The Bayh-Dole Act contained, however, in a more effective way, provisions through which benefits to the public may be envisaged.

A Parliamentary Standing Committee was constituted to submit a report based on the concerns of the stakeholders. The committee submitted a report which included the amended version of the bill. The bill was amended to include some provisions to ensure that the protected IP will reach the public. First, the bill added that the Government and any authorized person authorized can manufacture or make available the public funded invention.[34] The Government also has the power to issue non-exclusive licenses to any person for the utilization of the public funded intellectual property.[35] Such revisions enabled the government or any person to step in when the benefits of public funded research did not reach the public.

However, since the bill has been tabled the article does not go further into the details of the bill. Much later in 2019, the Government of India issued a draft of model guidelines on implementation of IPR policy for academic institutions. It is the first of its kind in India and has been delivered based on the National IPR Policy 2016. The National IPR Policy has several objectives and two of the objectives are to stimulate the creation and growth of Intellectual Property from R&D institutions and universities, through

[34] Parliamentary Standing Committee Report on the Protection and Utilisation of Public Funded Intellectual Property Bill, 2008, June 28 2010, *available at*: https://prsindia.org/files/bills_acts/bills_parliament/2008/SCR_Protection_and_Utilisation_of_Public_Funded_Intellectual_Property_Bill_2008.pdf (last visited November 30, 2022).

[35] *Ibid*.

measures that encourage IP generation[36] and to commercialise Intellectual Property.[37] The CIPAM was established under the Department for Promotion of Industry and Internal Trade, to deliver on the objectives of the National IPR Policy. They are tasked with the responsibility to generate and commercialise IPRs from the research institutions and the universities. The CIPAM also has the responsibility to create a platform where the creators and innovators of Intellectual Property Rights could connect with potential users, buyers and funding agencies, so that they could promote the licensing and technology transfers of their IPRs. This commercialization of IPRs, will result in creating IPR based products and services for the society. To facilitate the commercialisation of IPRs from research institutions and universities, the CIPAM published the 'Draft Model Guidelines on Implementation of IPR Policy for Academic Institutions.'

The guidelines recognise an Intellectual Property Rights Policy as the cornerstone of innovation and creativity for academia. It states that such a policy provides structure, predictability, and a framework for talented minds to do what they do best: create and innovate. The ultimate goal of these model guidelines is to promote student-led start-ups and ventures to protect and respect intellectual property. The larger objective of the Model Guidelines is to 'nurture the spirit of innovation' by translating the inventions generated in academic institutions into products, processes, and services, so that they can be commercially exploited for the benefit of the wider public.[38] It is perceived by the guidelines that this commercial exploitation of the academic inventions will transform the industry and society, by providing research-led education, promoting innovation, collaboration and fostering human values. Towards this end, the guidelines have identified six objectives. The first objective is to provide a framework to foster innovation and creativity in all areas of science, technology and humanities by cultivating new ideas and research.[39] The second objective as laid down in the guidelines is the protection of intellectual property rights generated in academic institutions by

[36] Objective 2, National IPR Policy, 2016, *available at*: https://dpiit.gov.in/policies-rules-and-acts/policies/national-ipr-policy (last visited on November 30, 2022).
[37] Objective 5, National IPR policy, 2016, *available at*: https://dpiit.gov.in/policies-rules-and-acts/policies/national-ipr-policy (last visited on November 30, 2022).
[38] Page 3, National IPR policy, 2016, *available at*: https://dpiit.gov.in/policies-rules-and-acts/policies/national-ipr-policy (last visited on November 30, 2022).
[39] Objective (i), Page 4, National IPR policy, 2016, *available at*: https://dpiit.gov.in/policies-rules-and-acts/policies/national-ipr-policy (last visited on November 30, 2022).

securing patent or other Intellectual property rights over the inventions.[40] The third objective is to lay down efficient and transparent mechanisms for control of ownership of inventions, Assignment of IP rights and for revenue sharing between the academic institution and the inventor.[41] The fourth objective is to increase the collaborations between academia and industry through better clarity on IP ownership and IP licensing.[42] The fifth objective is to help academic institutions achieve self-reliance in finance through the revenue generated from commercial exploitation of its invention. . The purpose of IP commercialization is also to augment the financial self-sustenance goals of the academic institution & its labs and to reward faculty and researchers.[43] The sixth objective is to establish an Intellectual property management cell in academic institutions to support the institute and its staff and students in all Intellectual property related matters.

It is surprising to note that the policy makers have completely ignored the public benefit aspects of commercialisation, despite a plethora of scholarly discussions that advise the institutions to focus specifically on public benefits. The guidelines have not recognised the important role of institutions in ensuring access to the public. It has also failed to incorporate the March-in-Rights in some form or the other into their framework. It also may be because of the fact that India already has a compulsory license provision under the Patent Act, which provides the Government the right to intervene in terms of price control or access regulation when the public has difficulties in obtaining any pharmaceutical patented product.[44] However, similar to its US counterpart, the compulsory licensing provisions have also been rarely used in India.[45]

5. Suggestions to Changes in Policy and Legal framework to Ensure Access

The 'ultimate objective' of patenting public funding should be to ensure access to the public funded inventions for public good. But, currently in India, we do not have provisions to effectuate the actual social benefits from public funded research by ensuring access to the public. Thus, the policy makers should have brought forward a set of model

[40] *Supra* note 41.
[41] *Ibid.*
[42] *Ibid.*
[43] Objective (v), Page 4, National IPR policy, 2016, available online at https://dpiit.gov.in/policies-rules-and-acts/policies/national-ipr-policy (last accessed on 30th November 2022)
[44] Indian Patent Act, 1970, s.92.
[45] Naval Satarawala Chopra and Dinoo Muthappa, "The Curious Case of Compulsory Licensing in India", 8 *Competition Law International* 34 (2012).

guidelines that could have addressed all these concerns existing around Intellectual Property Protection and Commercialisation. This is not to suggest that the issue of commercialisation of institutional IP is not pertinent. However, this model for Intellectual Property Protection and Commercialisation is not a fit policy taking into account the current needs of our public funded research system. What is required is the appreciation of underlying structural problems in our public funded research system and then taking policy cues from other developed countries and fine tuning them to our needs.

An IP Policy should relate to, support and operationalize the Institution's mission. Institutions have a range of differing missions ranging from education, research, revenue generation and societal engagement. IP commercialization and transfer of knowledge forms only a part of such missions and not their entire objective. Thus any model guidelines aiming to increase licensing of inventions must identify the problems that are preventing the institutions from entering into licensing agreements with the industries for commercialisation.

Here the model guidelines have not made any such attempt. One may attribute the absence of such provisions as already stated to the difficulties associated with determining beforehand the nature of licensing or commercial activities required for each invention. Licensing approaches can vary considerably from case to case. Several factors like the capacity of the institution, nature of the invention, licensee and industry affects the licensing practices. However, in spite of these differences, institutions can maintain certain core principles in all licensing activities which the guidelines could have identified.

For example, there have been several policy initiatives in the US to ensure access to pharmaceutical inventions. The NIH had issued a notice to the public funded institutions to pursue only non-exclusive licences to genomic inventions and to use exclusive licenses only when necessary "with the goal of promoting federally funded inventions' utilization, commercialization, and public availability."[46] Further, the Association of American Medical Colleges issued a document titled "Nine Points to Consider in Licensing University Technologies", which recognises that the Universities

[46] Best Practices for the Licensing of Genomic Inventions: Final Notice, *available at*: https://www.federalregister.gov/documents/2004/11/19/04-25671/best-practices-for-the-licensing-of-genomic-inventions (last accessed on November 30, 2022).

have a "social compact with the society" and they have to share their inventions with "the world's poor". It urged institutions to ensure that the public has access to the pharmaceutical products at low costs or at no costs, if necessary.[47] Additionally both these agencies along with the Centres for Disease Control and Prevention and other institutions also issued the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies. This policy stated that the universities had a pivotal role in improving the health of the public and urged them to include strategies for making such products available to the public especially in the developing countries by nut pursuing patent rights, or abandoning patents and by providing early publication for the wider dissemination of results.

The Indian institutions or policy makers could also take a cue from such initiatives. The model guidelines could have contained provisions that cautioned universities the factors to be considered while negotiating license, like to issue non-exclusive licenses, where greater commercial incentives seem necessary or ask the universities to weigh the benefits of nonexclusive licensing against the social cost of exclusive licenses or reserve the right of universities to use inventions for further research even if they are licensed or provisions or include strategies for fixing license fees etc.

The Guidelines should also have provisions to ensure follow up the status of licensed public funded inventions. The public funded institutions must regularly keep track of the inventions licensed by them. They have the responsibility to ensure that whether the licensing terms of the invention has been adhered to, whether adequate quantities of the product are being manufactured and whether the public has access to it at reasonable prices. If not, the universities must intervene and abandon the patent or give license to some other industry or fix the prices. The government must stress on these provisions either through the guidelines or they must make use of the compulsory licensing provisions in the Patent Act.

Further, there must be some provisions to ensure that universities do not deviate from basic research. The guidelines could have included some provisions for the identification and separation of basic research inventions from applied research inventions. Furthermore, developing countries like ours have a specific public need for

[47] "Nine Points to Consider in Licensing University Technology", *available at*: http://www.autm.net/Nine Points toConsider.html (last visited on November 30, 2022).

access to medicines and other social inventions. University research also often forms the knowledge base for an industry to carry forward further research. Hence it is imperative to ensure that such inventions are not locked in via IP or exclusive rights. The guidelines do not have any provisions that take into consideration the specific needs of India apart from the clause in the revised bill which ensures access to plant varieties.

6. Conclusion

It is an established fact that developing countries are more affected by several life threatening diseases. Hundreds and thousands of people die every year from diseases that could have been treated, but they have no access towards such treatments. The findings in the above sections indicate that a substantial chunk of innovation in such fields are taking place in public funded institutions. Thus, significant changes to government and university policies may be needed to promote access to drugs created using public funds. The institutions must adopt socially responsible patenting and licensing strategies by exerting proprietary rights only to the extent necessary for commercialization. Since it is the public that pays for the development for such products in the first place, they have substantial rights both legally and morally to get them at prices convenient for them.