

## Public Policy Reflection on Commercialization of Pharmaceutical Patents in India: A Legal Introspect

Payal Thaorey<sup>†</sup> and Anushree Mukte

Dr. Babasaheb Ambedkar school of Law, Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur – 440 001, India

*Received: 7<sup>th</sup> January 2024; revised: 5<sup>th</sup> May 2025*

Public policy, right to health, affordable medicines and patenting of medicines are closely knitted phenomena for fulfilment of individual and public interest imperatives. This article attempts to analyse the impact of patenting and commercialization of the medicines with and against materialization of right to health for all. The welfare aspects public policy that provides for availability and affordability of medicines for all and its applicability with respect to patenting and commercialization of medicines is examined in light of specific issues as follows-

- i. Primarily, whether the existing patent policy in specific is responsive to public policy in general.
- ii. Secondly, to what extent public policy shall be incorporated in commercialization of pharmaceutical patents?
- iii. Thirdly, to what extent commercialization of pharmaceutical patents can be compromised for execution of public policy?
- iv. Fourthly, is there any possibility of balancing mechanism wherein both, commercialization and public policy with respect to pharmaceutical patents can be maintained?

**Keywords:** Intellectual Property Rights, Patents, Pharmaceutical Patents, India, Public Policy, Right to Health, Commercialization of Pharmaceutical Patents, Compulsory Licensing, Affordability of Medicines, Economic-Monopolistic Approach of Patent

Public policy to its pith asserts social welfare at large. Policy making and implementation favouring a few is a suppositional situation in the absence of constitutional or other legal mandates. The patent system on the other hand advocates an exclusive monopoly to a few i.e. Patentee/s for invention. A serious conflict of interest is posed when one intends to establish a conducive environment for such conflicting public-private rights, especially in public policy aspects for a life necessity like medicines. Law and policy insist on adherence to the right to health but remain mute spectators toward the plight of patients due to failure to overcome private economic interests. Availability and affordability of medicine to all is directly proportional to the fulfilment of this right to health. Barriers to a disease-free life and a healthy life up to normal expectancy as such due to the patenting and commercialization of pharmaceutical products are nothing but a calculated assault on the health rights of individuals and society. This paper attempts to address the said scenario occupying public policy approaches with the

commercialization of pharmaceutical patents and vice versa and further makes an honest effort to identify the situations for balancing these conflicting rights.

### Meaning of Public Policy

Traditionally the basic aim of public policy is social welfare which is a goal-focused approach in its course of action undertaken by the government to deal with a public problem.<sup>1</sup> The scope of public policy touches every aspect of socialist governance. With the passage of time, the subject matter of these policy formulations is expanded yet the guiding principles remain unshaken i.e. public welfare. Public policy, in its simplest understanding, is, an action, or a plan of action, an instrument, or a means taken up by the authorities to address problems and cater to the needs of the public. It shall also be inclusive of planned allocation of naturally available means of production, or of those in public ownership, or of those available in exclusive private ownership but acquired for public purposes. Such a continuous, cautioned, concerted, and collective series of responses by the governing bodies towards public concerns establishes a structured underpinning of the policies. According to J. Kilpatrick, “Public policy is a system of laws,

<sup>†</sup>Corresponding Author: Email: payal.mundafale@gmail.com

*regulatory measures, courses of action, and funding priorities concerning a given topic promulgated by a governmental entity or its representatives.*<sup>2</sup> To consider the views by James E. Anderson, “*Public policy is a broad strategy the government uses to do its job, the relatively stable set of purposive governmental behaviors that address matters of concern to some part of society*”. It is thus a framework for the public good on a given subject that a government or an organization intends to pursue. It cannot go against common societal interests, though in a dictatorship or autocratic government, the whims and fancies of a person or a few persons may influence it.<sup>3</sup>

### **Conceptualization and Formulation of Policies**

Drafting of policies involves finalizing policy structure by considering its desired goals, related issues and challenges, enforcement and implementation plan, cost-effectiveness, identifying the socio-economic approaches and role of the sovereign authorities, cooperation at the organizational level, and hierarchical positions so involved.<sup>4</sup> The fulfillment of policy goals is materialized through the enactment of respective laws, rules and regulations, framing schemes, projects, and programs, and setting up administrative authorities (boards, commissions, panels, committees) for the same. Public policy not being just an abstract concept and has found its position in various legislations.<sup>5</sup>

### **Public Policy and its Constitutional Perspective in India**

A strong foundation for the said socialism can be found in provisions of the Indian Constitution, with concepts of socio-economic justice, public welfare, etc. to create a just and equitable society. The DPSP U/Arts 36 -51 of the Indian Constitution, states the minimization of inequalities with respect to facilities and opportunities stated U/Art 38 among other things to safeguard social order ensuring social, political, and economic justice. In the ideology approach Indian Constitutional provisions here are directed towards avoiding the resources and wealth in the hands of few, reflected under Art 39. Today, technological advancements and innovations are also subject matter of these constitutional rights be it Art 19 or 21, for it’s creators as well as for beneficiaries, i.e. Public.

The significant impact of the technology on healthcare facilities is, inter alia, obvious through

extensive scientific inventions, novel drugs and medicines, vaccines, medical devices, preventive medicines, and curative drugs which all can be safely regarded as ‘resources and wealth’ covered within the purview of Art 39<sup>6</sup> and hence well within authority of State to enable, disable, regulate or acquire the same in public interest. The function of State of state can be well understood in this regard with enforcement of public policy in light of “*doctrine of paten patrie*” as “*authority of State as a guardian can be validly assumed to cater to those who are unable to take care of themselves and is supported with an approach that State is more than just a nominal party in such cases. It establishes a strong public policy welfare approach where State can fully usurp rights in the legitimate interest to provide care to its citizens*”<sup>7</sup>.

### **Welfare Approach through Public Policies**

In general parlance, policies have different approaches based upon its goals. It may be restrictive, enabling, disabling or so on. As we follow Constitutional perspective here, it can be mentioned that the policies are expected to usually benefit the society at large. Though a lot of importance is given to social concerns relating to religion, infrastructure, social backwardness, freedom of speech, education economic growth, neo-developments etc., but none of these can be fruitful to individuals or even to society without good health. Public health, is identified as an imperative of the concerns U/Art 47 of the Indian Constitution, 1950. The full scale of human and fundamental rights comes to reality with the successful implementation of health legislation, guidelines and facilities for all.<sup>8</sup> The concept of health is extensive to cover within itself, the available, affordable therefore accessible medicines and medical treatment. Invention of medicine/medicinal treatments, devices, products, processes and the knowledge-based rights so associated with it form subject matter of patent as an intellectual property right. And the impact of IPRs - patents is visible on the availability and affordability of such medicines. Here, to narrow down the discussion, let us take the recourse of intellectual property rights into consideration discussing its interface with the availability and affordability of patented and further commercialized medicines.

### **Grant of Pharmaceutical Patents**

Intellectual property rights are a system of legal framework that includes identification, protection, and

administration of intangible rights in the form of copyrights, patents, trademarks, trade secrets, geographical indications, integrated circuits and semiconductors, plant variety, biodiversity etc. The basic rationale behind the granting of such IP rights is to ensure individual's private and exclusive rights for the creation, thus encouraging innovation. There is always an intersection of public policies with such private laws, to be precise here, with individual rights as apparent in fundamental rights and the DPSPs. This concern is repeatedly observed in cases of patenting policies in India. "*A Patent is an exclusive right granted by a government for invention,<sup>9</sup> which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution or offers a new technical solution to the problem*".<sup>10</sup> "The effect of grant of patent is quid pro quo. In *Raj Prakash v Mangat Ram Choudhary* [1] and ors., 1990 F.S.R 181, Court stated- Quid is the knowledge disclosed to the public and Quo is the monopoly granted to the patentee."

Grant of patent ensures the creation of a monopoly rights U/Art 48 of the Indian Patent Act, 1970 in favour of the inventor for the invention product and / process as included under Patent (Amendment) Act, 2005 and prohibit free flow of invention's benefit to all. The sky is the limit to discuss the subject matter scope of inventions. These inventions have a deep impact on day-to-day human existence as they may start from a simple toothbrush and extend up to a moon lander. The protection of IP creates legal rights as the inventor can conveniently exclude others from use of the creation as well as economic profits at a larger scale by commercialization.

The exclusion is not absolute but concerning as patents have a widened scope to include health and health care facilities within itself consequently attracting an angle of 'paying capacity', of an individual to avail such patented commodities from health care sector. Inventions when patented may no longer remain affordable, which might be fine for luxuries but can't be so with respect to life necessities, especially medicines, unavailability of which shall be denial of the right to health in particular and right to life in general, without any due process of law as decided in case of *Murli S. Deora v Union of India and Others* (AIR 2002 SC 40).

The patent system supports the commodity market and commercialization making the patented products costly and unaffordable to general public. With the

creation of a monopoly patentees are earning exorbitant profits but serious consequences are seen with respect to pharmaceutical products in this regard. In order to curb such an unaffordability, State is expected to intervene and shall find out the best possible balancing mechanism through its policies. Law and policy are expected to maintain the balance of interest between the haves and have-nots within the society. One of the features of Indian patent system is maintaining public interest and ensure utility along with incentivizing innovations and trade development. The existing patent system has created the monopoly that has led towards denial of accessibility to all. Once this patent right i.e. Monopoly expires, the invention is available in public domain but it does not resolve the issue. The main problem is faced when the product is available as per need of the public. The necessity of patented medicine cannot be relevant to and dependent upon expiry of term. It may arise anytime. We have experienced such a problem severely during pandemic in such a scenario, if patented medicine is unavailable to public due to commercialization, it is basically failure of the utility concerns mentioned patent law.

It is agreed that patent monopoly over medicines as a right of patentee is a well-established right. But looking at the nature of invention, i.e. Medicine and its utility to public for saving life or for betterment of life, it is very well argued that, limiting such monopoly rights is strongly justified, but not absolutely. The benefit of bias is not expected to be served just to an individual or just to society but to both to a compatible degree.

Let us evaluate patent-related policy with public policy and relevant concerns about pharmaceutical patents with the aspects of commercialization in further discussion. Patent monopoly and utility of patent has to go hand in hand. Both must function together with public policy approaches of regulation and welfare of society. The social utility approach is the one that can be seen as ray of hope for balancing conflicting interests of medicine owners and the poor patients in the society.

### **Approaches to Patent Policy**

The most obvious approach with respect to patents is rational one. Putting the policy making related to patents under a microscopic lens, the most obvious approach is a 'rational approach'<sup>11</sup> which advocates maximization of the efficiency of an invention by

polycymaking. However, the rational approach of public policy implementation does have its limitations in situations of scarcity of resources, emergencies, catering to reasonable needs of the few, or even in cases of resorting to optimum socialism. Hence, along with rationality, patent policies are majorly following the 'incremental approach'<sup>12</sup>, i.e. a stepwiseries of evolution in patent-related policies that are responsive to continuously changing current situations.

In its regulatory approach<sup>13</sup>, patent policies have successfully guarded the misuse of inventions and due adherence to patentee's rights, by, an exclusive decision-making power towards economic recourse of one's patent but not unfettered right. Basic need of pharmaceutical patents is about the question of life and death. A patent policy which exclude others can not apply absolute blanket ban to all from accessibility due to commercial costing. The monopoly and exclusion are based on premise of protecting creativity and to maintain regulatory practice by State. The same shall not be the rationality for the denial of medicines to the needy.

Consideration of public interest in regulatory policy approach can be evidently found within the provision of the Indian Patent Act, 1970 in attribution to,

- (i) The concept of utility and usefulness of patent for and by public at large depicts rational approach
- (ii) Non-patentable inventions as provided under Sec 3 & 4 are also seen in rational approach
- (iii) Grant of patents to be subject to certain conditions as specified U/Sec 47 where regulatory approach so followed.
- (iv) General principles applicable to working of patented inventions U/Sec 83, is a regulatory approach of policy.
- (v) Compulsory licensing U/Sec 84 is the best example of regulatory approach of patent policy.
- (vi) Revocation of patents by the Controller for non-working U/Sec 85 also shows regulatory approach.
- (vii) Special provision for compulsory licenses on notifications by Central Government as per Section 92 is a regulatory approach of policy.
- (viii) A compulsory license for export of patented pharmaceutical products in certain exceptional circumstances U/Sec 92A, is a regulatory approach of policy.
- (ix) Use of inventions for purposes of government and acquisition of inventions by central

government U/Sec 100, 102 also follows regulatory approach.

- (x) Certain acts are not to be considered as infringement as specified U/Sec 107A depends upon the rational approach.
- (xi) Mandate for periodic renewal Sec 53, The Patent Rules, 2003, Rule 80 is an approach of regulation.

A policy approach that can regulate and balance the competing rights under patent system is the only option because patents ate statutory rights and the policy approaches of State enforces these rights. A patent formally allows the patentee the iron gripped control to monopolize the market and secure the commercial benefits. Grant of patent provides bundle of rights namely right to use, exploit, transfer, commercialize, make use. Make exploit and exclude others. These rights are merited against or in return for disclosure of the invention to the public for all intent and purposes.<sup>14</sup> These are subject to fulfillment of patentability criteria. The bundle of rights is certainly beneficial during its life but also after expiry, if it is properly implemented and commercialized. However, it has its own restrictions U/Sec 3 (b) i.e. If commercial exploitation of an invention operates against public order or morality or causes serious prejudice to human, animal, or plant life or health or to the environment, it shouldn't be patented.

Patent legislation, irrespective of its monopolistic rationale does not veto concerns towards public interest. Particularly with respect to health rights and our final product in question i.e. medicines as it holds the status of necessity of life. It would be uncontentious to establish that the idea of public policy and its objective of fulfillment of public interest, and basic right of human beings of safety, life, health, access and affordability of medicines, healthcare devices and technology etc. is very well perceivable in patent policies. There exists a predominant aspect of public interest under patent public policies. The rationale of Patent system in India certainly aims at incentivising innovations but ascertains to protect public interest at the same time. How so ever commercialization is argued in favour of pharmaceutical patents, we have seen the public interest fulfilled in steps like eradication of polio in India.<sup>15</sup>

However, the justification sought by pharmaceutical companies for such exorbitant cost is

the expenses incurred for Rand D, infrastructure establishment, maintenance of quality of medicine, marketing-branding and legal-regulatory compliances. The question arises that can we achieve public policies' welfare goal when the pharmaceutical patents are duly commercialized with huge expenses. If yes, then there is a dire need to inculcate the public interest approach for the humanitarian availability of drugs for all without discouraging innovations. The scenario has become of utmost importance as the world has already faced an unprecedented COVID-19 pandemic when these private patented profiteering aspects overridden the public need for drugs for all. Hence, the spectrum of such application of policy approach needs to be 'brought into being and streamlined' for commercialization of pharmaceutical patents.

### Drug Price Control Mechanism

Looking at the population, diseases suffered, cost of treatment, and paying capacity of the maximum number of populations, the Indian government cannot be complained of being completely ignorant towards understanding of the issue of unaffordability of drugs, at least for essential medicines. Drug Price Control Mechanism and National Pharmaceutical Pricing Authority (NPPA) together have established a mechanism for putting an upper cap on pricing of the scheduled medicines. A country-particularized National List of Essential Medicines<sup>16</sup> based on wholesale price index<sup>17</sup> enlist the medicines which shall be sold below the price ceiling at an affordable cost with assured quality, as notified by NPPA India from time to time, including pharmaceutical patent also.

### Primacy of Commercialization over Public Policy with Respect to Pharmaceutical Patents

The phenomenon of rapid and advanced growth with research and development is outstandingly identifiable in drugs and pharmaceutical industry with strictly protected IP rights. The cost of development of new drug is 10-15 million rupees in India<sup>18</sup> coupled with the development risks and cut-throat competition. The duration needed from initiation to approval of drug is roughly at an average of 11.8 years.<sup>19</sup> The results of these researches are subject to risks of clinical trial failures before commercialization, market failure after commercialization, blanket ban due to governmental policies etc. Pharmaceutical industry is one of the most booming sectors because of the tremendous

Table 1 — Growth of pharmaceutical industry of India

Financial Year	Turnover (Rs. in Crore)	Growth Rate
2017-2018	2,26,423	3.03
2018-2019	2,58,534	14.18
2019-2020	2,89,998	12.17
2020-2021	3,28,054	13.12
2021-2022	3,44,125	4.89

development in its technological and manufacturing capabilities as compared to 1950s and pharmaceutical patents play major role in this position. This can be understood with simple numbers<sup>20</sup> concerning the growth observed. India is the 3<sup>rd</sup> largest global pharmaceutical producer, with total annual turnover of Rs. 3,44,125 crores (USD 42.34 bn) in financial year 2021-22. India accounts for vaccine production varying from 40 to 90% range<sup>21</sup> also known as a largest supplier of generic medicine with 60,000 different generic brands across 60 therapeutic categories and accounts for 20% of the global supply.<sup>22</sup> The picture can be made further clear about the growth of pharmaceutical industry of India with following figures of pharmaceutical sector's growth at Current Prices (Table 1).<sup>23</sup>

Morally, such product is availed commercialized, the last thing on earth pharmaceutical patentee imagine is availability of drugs to all without expected profits. However, due to commercial and legal parameters such drug at times becomes unaffordable. The possible parameters under consideration for commercialization are-

- (i) Cost incurred for R and D- product developments,
- (ii) Cost incurred for clinical trials
- (iii) Cost incurred for development of techniques to scale-up production prior to taking the results of research to market
- (iv) Cost incurred for extensive marketing practices
- (v) Cost incurred for legal compliances
- (vi) Cost incurred for failures
- (vii) Cost for continuing research further or other research
- (viii) Duration of patent for the medicine and renewal
- (ix) Extent of technology transfer under assignment or licensing with local working of patent<sup>24</sup>.
- (x) Non-strategic use and longer duration of maintenance<sup>25</sup>.
- (xi) The prescription pattern followed by healthcare professionals

These vital parameters may form the final pricing policy of pharmaceutical giants. A patentee of drug is expected to forgo his/her rights to remove barriers to the unavailability of drugs. But rare are the cases that we have observed such steps. With such a huge share and growth of pharmaceutical sector, and with wide variety of medicines, bulk drugs, biosimilars, etc. when patented drug is made available in commercial market, it results in invariably high price. Moreover, if a pharmaceutical company successfully resorts to evergreening i.e. the making of minor modifications in a drug structure or formulation of patent, commercialization shall further lead to unavailability of such patents at affordable cost to public at large for longer time. Commercialization of patent ideally shall ensure to incentivize innovation and promotion of technology yet it seems to operate otherwise when availability and accessibility is considered, as, none of the parameters concerns with equitable availability of the drugs. Accessibility is part of a public policy but the same is not achieved due to commercialization.

#### **Primacy of Public Policy over Commercialization of Pharmaceutical Patents**

The horizons of protection of public health at large or even individual health rights are overspread and proliferating. At this point of juncture, public policy approaches intersect with and operate against exclusive control and commercialization rights of the patentee. Here public law enters into the private law and bars the latter from actualizing its normal legal consequences.<sup>26</sup> In this aspect, right to health which is sacrosanct right under Indian constitution and the overall constitutional imperatives aiming at extensive social justice mandate that drugs, of whatever price shall be accessible, available, and affordable to all, yet a private patents rights on pharmaceuticals allow for monopolistic pricing, which puts them out of reach of those who need them the most. Chronic and life-threatening diseases are very common worldwide. Let it be regular situations, pandemics, or specific life-saving medicine, direct consequences of patenting and commercialization are visible with unaffordability-unavailability either to all or to the respective pool of patients. One may argue that right to receive affordable medicine is too exaggerated to compromise with profits of patentee but this can be negated by putting forth the status of health of population in India, for instance-

- (i) Around 77 million people above age of 18 years suffering from Type 2 Diabetes.
- (ii) Nearly 25 million are pre-diabetic, making India a Diabetic Capital of The World.
- (iii) More than 50% of people are unaware of their diabetic status which leads to health complications if not detected and treated having increased risk of heart attacks and strokes<sup>27</sup>. And the median average annual direct and cost associated with diabetes care were estimated at ₹ 25,391<sup>28</sup> whereas the average life-time cost of all drugs used in diabetes management is estimated at ₹ 19,45,135<sup>29</sup>.
- (iv) Estimated 17.9 million people died from Cardio Vascular Diseases in 2016, representing 31% of all global deaths. Of these deaths, 85% were due to heart attack and stroke, 45% of deaths in the 40-69-year age group in India.
- (v) The estimated number of incident cases of cancer in India for the year 2022 was found to be 14,61,427 (crude rate:100.4 per 100,000) i.e. one in nine people are likely to develop cancer in his/her lifetime. Lung and breast cancers were the leading sites of cancer in males and females, respectively. Among the childhood (0-14 year) cancers, lymphoid leukaemia (boys: 29.2% and girls: 24.2%) was the leading site. The incidence of cancer cases is estimated to increase by 12.8 per cent in 2025 as compared to 2020.<sup>30</sup> With the average cost of treatment estimated up-to Rs. 5lakh.
- (vi) Around 10% people living in rural areas have no access to essential medicines and only 19% have a health insurance.<sup>31</sup>

Moreover, where India was aiming at 80% reduction in Tuberculosis cases till 2025, India has 199 TB patients per lakh population, contributing 27% of the global TB cases<sup>32</sup> with gap in the budget allocated and actual expenditure resulting into the cost of medicine from primary symptoms to 1 years post treatment is 26,500 to 30,000 per patient.<sup>33</sup>

In this scenario of wide patient pool and exorbitant costs of treatment, public interest imperatives insist upon public ownership of the means which shall be universally available medicines. Looking to the theoretical approach of the same, as Karl Marx<sup>34</sup> propounded, no resource shall be restricted at the hand of few as against Lockean concept<sup>35</sup> of monopolistic rights awarded against the labour so exerted. An individual, though is an important part of

society owning a drug, these policies are predominantly concerned with ensuring greater good rather than individual benefit. Hence, it is difficult to justify purely monopolistic commercialization in light of public policy. Even to consider contemporary economic principle of the TBL- Triple Bottom Line approach which establishes that along with financial profit, its social and environmental impact shall be always evaluated. The 3 Ps, profit, people and planet have to operate together.<sup>36</sup>

To succeed with profit motives of pharmaceutical giants, practices such as resorting to evergreening, assignment or licensing without clear cut technology transfer, anti-competitive practices, and drafting of Markush claims<sup>37</sup> are observed which creates bar to free flow of benefit to all or perpetual patenting as an antisocial option. Attempt for evergreening of patent has been discouraged and rights are gracefully established by Indian judiciary's *ratio decedendi* against such practice is a notable stand here which is extensively discussed IN Section 3 (d) of Indian Patent Act, 1970, 2(1) (j), 133, 24A and writ jurisdiction of Constitution of India under Article 136 in case of *Novartis v Union of India and Others*, AIR 2013 SC 1311, in favour of public interest at large. Discussed as, "*When a public policy is drafted, its intent, enforcement, judicial interpretation shall be based on prevalent requisites of the general public. The final product as a result of invention must involve technical advancement and shall ensure having economic significance*". A due importance to economic aspects exists in drafting and implementation of public policy with respect to patents.

Curbing the reach of patent rights may result into discouragement to innovation and disclosure of invented drugs and it is a perpetual threat. Indian Patent Act, 1970 entitles the patentee to exploit his patent and exclude non-inventor from unauthorized use. The argument is whether this concept of exclusion of non-inventors is wide and absolute enough to exclude/deny the drugs to the patient who might lose his/her life or have a life full of ailments due to high cost of drugs? Another question is whether this situation shall keep up to society at large that results into gross denial of right to life and health which is reflected into society with innumerable diversified pool of patients?

One may argue to suspend patent rights altogether for drugs, howsoever 'egalitarian' it may sound, it

doesn't seem practically possible as it will be a total prohibition, hypothetical, hence constitutionally invalid as provided under Reasonable Restrictions to Art 19 (2). Whenever private rights are involved, generally it gets difficult for judiciary to rely upon the wide-reaching arguments. Yet Indian judiciary have considered some foreign decisions<sup>38</sup> that makes compelling arguments in favour of ensuring public interest along with pursuing innovation and commercialization as an intention for patenting. Viewpoint of Indian judiciary is also notable as mentioned in case of *F. Hoffman-La Roche AG v Cipla Ltd. HC Delhi*, 19 March 2008, that, in matters of access to medicine especially lifesaving drugs, as such medicine though available in market, but will be inaccessible due to injunctions, the degree of harm, every chance of recovery denied would snuff out combined and cause greater loss than just monetary.

### Issues and Challenges

Considering all the above factors as well as pure monopolistic approach behind pharmaceutical drug patenting and the expense so involved in the whole process; availability, affordability, and accessibility to these patented pharmaceuticals has gone astray. Hence, following are some major issues observed-

#### Conceptual Irrelevance

As pharmaceutical patentee's rights emerged with monopolies, inflated prices, and procrastination in generic or biosimilar competition, the initiative intended to resolve the unavailability due to unaffordability issue for general public holds no ground. The theoretical understanding and parameters for commercialization of pharmaceutical patents and those for public policy approach are completely different from each other. The problem of unavailability of pharmaceutical patents due to commercialization is conveniently excluded, ergo making it difficult to define horizon and depth of public policy inception in commercialization of pharmaceutical patent and its further availability when social needs are imperative.

#### Tussle Between Right to Health and Right to Earn Profits

Administration and need of a drug are not a choice-based phenomenon but a right based. Although it is possible to do away with consumer goods, but with an exception of drugs for health. Insurgency of restriction all around use of patented and commercialized pharmaceutical patents has posed questions as to the possibility of practical implementation of right to health

in contradiction with right to earn profits, if right to health having higher persuasive value than right to earn profits. The same perspective shall be prudently and necessarily applicable in cases of pharmaceutical patents. If no, then why no aspect of commercialized pharmaceutical patents is patient-centric or sensitive towards them. And thereby not coming in tune with public policy notions. However, what is essential is to consider that accessibility and affordability of pharmaceutical patents must be ensured by patient-centric criteria, whereas commercialization stands in contradiction thereby creating issues of equitable distribution, accessibility, and availability of drugs.

#### **Income and Costing – The Disparity and Affordability**

A joint effort by National Pharmaceutical Pricing Authority and Drug Price Control Authority by implementation of National List of Essential Medicines is a positive step which provides cost effective drugs to public. *To look into viability of the same, the position is understood by following chart that depicts current status of inflation for healthcare for year 2023.*

According to a news report, “It’s believed that a middle-class Indian is just one medical emergency away from becoming poor”.<sup>39</sup> It can be safely believed so because, per capita income in India for year 2022-2023 is Rs, 98,374<sup>40</sup>, with RBI projecting headline inflation at 5.1%<sup>41</sup>, whereas medical inflation rate is at 14%<sup>42</sup> which is way too high and difficult to match with such low per capita income. Such disparity in income rate and inflation consequently leads to consumers’ incapacity to pay for costly pharmaceutical patents.

NPPA has amended the National List of Essential Medicines with 10.7% inflated prices of essential drugs and irrespective of State expenditure on healthcare, 63% of total medical expenditure is snatched out of individuals’ pocket.<sup>42</sup> To consider an example, for a common disease like cancer, out of pocket expense for an individual is approximately at least of Rs 331,177<sup>43</sup> which is already way too higher than annual income of a middle class or a person below poverty line. Irrespective of the fact that 4 anticancer drugs are included in National List of Essential Medicines,<sup>44</sup> yet price for an injection of *trastuzumab* (440mg/50ml) which is an essential lifesaving drug for cancer treatment costs Rs. 66,790/- (in 2022)<sup>45</sup>, proving inadequacy and contradiction between objectives and impact of National List of Essential Medicines. Therefore, it is proved that when an average income of

a person is 98,374<sup>40</sup> and if the cost of medicine per injection is 66,790/- then certainly this is going to affect right to life of that person vis a vis the patented price of that drug. Now, the discussion put forth is how can government afford to have such a costly price when the income is so low rather it can be considered that why the government is not working in stabilizing the price mechanism in proportion with the average income of the public at large. The existence of such issue prima facie shows that right to life is commonly compromised to ensure profits for pharmaceutical patents owners and pharmaceutical giants. This leads to failure of holistic efforts towards healthcare and finally commercialization in healthcare with relative factors overriding the public policy.

#### **Status of Medicine under Patents**

Irrespective of pricing policies, there is no scope of manufacturing a cheaper version of the commercialized pharmaceutical patents during the existing term of protection. A drug when patented and commercialized leaves no scope for possible imitation which can be less costly even if it is unavailable and unaffordable or required for emergency medical treatment. Any ‘colourable imitation or immaterial variation’ amounts to infringement<sup>46</sup> and consequently liability. As per Sec 104, “*A colourable variation or immaterial variation amounting to infringement is where an infringer makes slight modification in the process or product but in fact takes in substance the essential features of the patentee’s invention*”. So the scenario lies that pharmaceutical patents is needed but is unaffordable and also disallowed for its cheaper availability in any possible prospect. There is no aid to public interest approaches either by the patentee himself or even by the government. On one hand, Constitution of India, 1950 realm explains life and health is of utmost of Importance, but the rationale behind patent is certainly to earn profits. In such extreme situations, how constitutional mandates be justified? A colourable imitation shall have been permitted to certain extents in exceptional situations with regulation but this effort has not been taken by government so far. Does it mean they are applying to narrow interpretation of public policy which is always superseded by commercialization? If at all government wants to be responsive to such situation a small amendment with utmost precaution preventing abuse of such provision can solve the problem to greater extent.

### Incomprehension towards Welfare Doctrines

State as a welfare institution conforms to itself authority to take protective steps against the right of non-state players to fulfil greater social interest under the inherent though not absolute authority as *parens patrie*. An obvious application of this doctrine is applicable in favour of public health to ensure availability and affordability of pharmaceutical patents. Taken by shock, there was sheer non-application of this concept to avail life-saving drugs, and further shocking was non-application in the COVID 19 health emergency situation. Availing the affordable pharmaceutical patents could have been immediately and effectively possible only with State's intervention in capacity of guardian for its citizens. A simple application of authority under social justice and equitable distribution of resources still inertly lies in the books when the need of affordable life-saving drugs to all is questioned. Is it not possible to establish a notional extension of concept of *parens patrie* to successfully apply the same for citizen as a child of State and articulate its policy on the same lines to bar the commercial abuse of pharmaceutical patents.

### Developed, Developing, and Underdeveloped Nation's Saga

Orientation of international patent protection laws with respect to drugs is not nation-specific as it establishes common minimum standards of protection are established under Agreement on Trade Related Aspects of Intellectual Property Right, 1995, (TRIPS) Art 2.1, 9.1 for all member states, whereas need and availability for drugs differ nation wise. The common protection standards have created hurdles against availing such pharmaceutical patents for public purposes. Similarly, price policy mechanism varies on grounds of resource availability of respective country - developed, developing, or underdeveloped, also for the reason of paying capacity, access to resources, health facilities such as insurances, free treatment etc. Expensive price policy mechanism for pharmaceutical patents exists in developed nations however in developing and underdeveloped nation's pricing policy of drugs is expected to meet the affordability criteria. However, when there is commercialization of pharmaceutical patents, the criteria that are applicable are more on the lines of favouring and benefiting to inventor irrespective of the thought whether inventor belongs to developed, developing or underdeveloped nation. On one hand,

the price policy mechanism expects that pricing of life saving drugs needs to be as per status of country, on the other hand commercialization of pharmaceutical patents is done irrespective of status of country and creates a tussle between inventor's benefit as against affordable pricing of such drugs across that country.

In such situation it can be argued if it is permissible to import such unaffordable pharmaceutical patents from those member states where affordable drugs are available particularly when a country is a member country of WTO and is internationally governed through TRIPS which insist upon national treatment to all states along with other principles under Articles 3-5 of TRIPS. Considering international approaches and application of intellectual property rights regime, if a pharmaceutical patents is availed at cheaper price in any of the member states to its own public by any domestic legislation, then it would be obligatory upon that member state to avail the same cheaper priced, patented and commercialized drug to all other member states at the same cheaper price which may not be practically possible due to paucity of resources and economic barriers resulting into an allegation of non-adherence to international principles suffocating the possibility of affordable pharmaceutical patents from all possible fronts.

### Procedural and Enforcement Approach Issues

An option to reap fruits of economic significance by patent commercialization is resorted with licensing, preferably voluntary. But pharmaceutical firms either having a *mens rea*<sup>47</sup> to blockage the drug tend to rubbish attempts made for licensing or tend to turn down the same over amount of royalty so expected. It is unreasonable to say that attribution of patent rights solely has consequential impact on commercialization. Yes, the blockage as mentioned may operate, yet, even unregistered invention can be very well commercialized and still confirm only to profit motives.

Patent shall conform to utility for commercialization and this prospect is ultimately observed with working .i.e. patent must be used, commercially - locally, and no patentee shall sit inert with his invention /non-working of patents by the requisite disclosures as specified U/Sec 146; Rule 131, Form 27. This disclosure includes details as to commercial exploitation of patented invention to the adequate extent. Patentee shall yearly file the statement of working of patent to keep his patent rights alive which shall contain details as to

manufacture of patented invention and adequate availability at commercial and local level. Steps must be taken for licensing and sub-licensing and if not so, reasons for non-working shall also be quoted. In such periodic filing, specific and concrete disclosure are avoided by pharmaceutical companies to keep up the competitive edge. Such practices not only bar the disclosure which can be useful for further research but also results into unsuccessful check on the availability of pharmaceutical patents.

#### **Compulsory Licensing**

Compulsory licensing of patent by government is one of the possibilities by which availability of affordable pharmaceutical patents can be ensured. Such license of pharmaceutical patents can be issued for government use U/Sec 100 or in public interest etc U/Sec 92 of the Indian Patent Act, 1970 in case of non-filing of working statement for consecutive three years along with other requisites. Presently, India has witnessed one and only compulsory license to “Nexavar”, a kidney cancer medicine since the application of Patent Act, 1970 and the relevant revision in 2005. As it can be conveniently observed here, primarily patenting and commercialization bars access to affordable drug, and the powers to ensure availability by compulsory licensing is hardly used by the government. The issue posed a serious question during COVID 19 outbreak where judiciary intervened invoking Sec 92 and 100 of Indian Patent Act, 1970 and discussed “Potentiality Of Compulsory Licensing For Vaccines And Essential Drugs” namely Remdesivir, Tocilizumab, Favipiravir etc. which resulted in delayed but available vaccines and drugs irrespective of existence of patent as discussed in *Re: Distribution of Essential v Unknown*, W.P.(Civil)No. 3 of 2021, yet was highly insufficient considering the patient pool and the need of drug as against loss of life of public at large.<sup>48</sup> Non-issuance of compulsory license did medically and financially affect the COVID 19 patients.

Furthermore, the present proposal to amend Patent law in this regard shall progressively complex this issue as the annual filing of working of patent is proposed to be extended to 3 years under Patent Amendment Draft Rules, 2013, which shall put public in a helpless position to check working of drug patent and request for optimum availability and utilization of such lifesaving medicinal invention. Patent act in letters tries to fulfil notions of public policy but the conservative approach under the Act within itself

ignores and automatically restricts the spirit of public policy approach. At least in extreme health emergency like pandemic, the constrains and mandates causing barriers to compulsory licensing of pharmaceutical patents, or to active government use needs to be amended.

#### **Conclusion**

It can be said that emphasis on public health policy does not negate economic development but rather assists it. But public interest has no paramountcy with respect to commercialized pharmaceutical patent. Exiting law and policies needs careful and due extension to curb the commercialization against the cost of public health. Legislative bias in the form of monopoly has worsen the situation. Availing low cost pharmaceutical patents to all is a choice of pharmaceutical patentee and the factors creating this imbalance are yet to be addressed by State while drafting health policies at the fullest due to limited operation of public policy against pharmaceutical patents.

With the rampant health crisis, it has become imperative to act upon extension of concept of public policy to avail the pharmaceutical patents from the clutches of commercialization for social welfare. The sheer responsibility lies with patentee to revisit his profit-making priority over at least humanitarian emergencies and the fatalities. If it is not so addressed, unexpected and harmful impacts of fanciful individualistic notions will be repeatedly created and protected. It is very amusing to note that such denial of pharmaceutical patents in the garb of monopoly has become more important than human life. But social responsibility of pharmaceutical companies towards citizens of the country as providers of life-saving drugs seemed missing.

To sustain and prosper, pharmaceutical companies in India need to formulate strategy only to maximize their profits and are misusing the supportive approach of Government towards economic growth. To foster this situation further, public policies seem to have limited operation against such private profiting rights. A stringent profiteering approach at least with respect to pharmaceutical patents needs to be opted out from, voluntarily/compulsorily. We need to seriously consider how much public policy can form part of commercialization and how much commercialization can be part of public policy. But all the imperatives of public policy approach are left out while commercializing but imperatives of economic benefit

of pharmaceutical patentee are seen operating predominantly. Even in an extreme emergency like pandemic, unavailability of drugs and health care facility was a pathetic fact to be pondered upon by the State. Patent policy implementation is understood in furtherance of socio-economic equity and justice, and there is need to specifically address that policy for commercialized pharmaceutical patents must conform with these Constitutional imperatives without succumbing to pure monetary rights.

### Suggestion

With reference to the above discussion, following suggestions are made -

- (i) Conceptual relevance between public policy and the existing relevant parameters to commercialization need to cover the impact of loss of life and the rippling effect on national economic growth due to unavailability and unaffordability of drugs.
- (ii) The aspect of greater social responsibility needs to be infused legally and socially through awareness and amendments in the minds of pharmaceutical patentee. Pharmaceutical patent owners need to be guided by patient's right-centric approach at least with respect to life saving drugs and emergencies like pandemics.
- (iii) Imperatively distinguish need for drugs from need for other consumer products.
- (iv) Avoid blatant application of legal principles without concern towards nature and purpose of pharmaceutical patents just as an ordinary consumer good.
- (v) Restrict cost of marketing/branding by government mandates by identifying and capping post manufacturing expenses for price reduction.
- (vi) The National List of Essential Medicines shall be revised yearly in conformity with WHO Model List.
- (vii) The criteria of availability shall be connected with income of the patients in need of pharmaceutical patents. An unaffordable pharmaceutical patents is unavailable one. Hence, price of drugs shall be allowed to be objectively varied on case to case basis.
- (viii) Initiate steps for extensive access of drugs to all irrespective of TRIPS obligations which may be waiver of patent rights and compulsory licensing reasonably considering national interest rather

than blindly adhering to rigid international obligations.

### References

- 1 Galston W A, *Philosophical Dimensions of Public Policy* 189 (Routledge, New Delhi, 1<sup>st</sup> edn., 2003)
- 2 Kilpatrick D G, in *Definitions of Public Policy and the Law*, Available at <https://mainwebv.musc.edu/vawprevention/policy/definition.shtml>, (accessed on 10 September 2023).
- 3 James A E, *Public policymaking an introduction*, Sixth edition. Boston, Houghton Mifflin, (2006) 6.
- 4 Mukesh Research scholar, Maharshi Dayanand University, Rohtak, *Public Policy Making in India, International Journal of Advance and Applied Research*, 2 (22)
- 5 Arbitration and Conciliation Act, 1996, (Act 26 of 1996) Section 34. (2) (b) (ii): Arbitral Award may be set aside if the court finds that the arbitral award is in conflict with the Public Policy of India, The Indian Contract Act, 1872, (No. 9 Acts of Parliament 1872) Sec 23.
- 6 Relevant part read as: Certain principles of policy to be followed by the State: The State shall, in particular, direct its policy towards securing- (b) that the ownership and control of the material resources of the community are so distributed as best to subserve the common good; (c) that the operation of the economic system does not result in the concentration of wealth and means of production to the common detriment.
- 7 *Chmanlal Sahu v Union of India* (1990) 1 SCC 613; *Heller V. DOE* (509) US 312.
- 8 "Even principles of equality shall stand relevant when government provides health facilities". Held in, *LIC of India v Consumer Education and Research Centre*, AIR 1995 SC 1811; "providing adequate medical facilities for the people is an essential part of the obligations undertaken by the government in a welfare state", *Paschim Banga Khet Mazdoor Samity*, AIR 1996 SC 2426.
- 9 Sec 2 (1) (j), Indian Patent Act, 1970, "invention" means a new product or process involving an inventive step and capable of industrial application.
- 10 Indian Patent Act, 1970 ( Act 39 of 1970), Sec 2(1)(m); World Intellectual Property Organization, Available at <https://www.wipo.int/patents/en/>, (accessed on 20 September 2023).
- 11 Dye T R, a Professor Emeritus of Political Science at Florida State University, 'a policy is rational when it is most efficient, that is, if the ratio between the values it achieves and the values it sacrifices is positive and higher than any other policy alternative.'
- 12 Lindblom C E, "The Science of Muddling Through" in *Public Administration Review*, a journal of the American Society of Public Administration, (1959).
- 13 Hill M & Hupe P, *Implementing Public Policy: An Introduction to the Study of Operational Governance*, 12 SAGE Publications Ltd., New York, 3<sup>rd</sup> edn., (2014).
- 14 Narayanan P, *Patent law*, (Eastern Law House, 4<sup>th</sup> edition, 2017) 1.
- 15 Polio Eradication Initiative, World Health Organization, available at <https://www.emro.who.int/polio-eradication/news/polio-free-india-it-seemed-impossible-until-it-was-done.html>.

- 16 Published by Ministry of health and family welfare in year 1996, revised in years 2003, 2011, 2015, 2022.
- 17 “Essential drugs are those that are therapeutic and are used to treat common medical ailments and are available to treat patients with immediate effect.”
- 18 Bajaj J S, Drug development in India, *Indian Journal of Physiology Pharmacology*, 25 (2) (1981) 95, PMID: 7287145.
- 19 Is the patent system a barrier to inclusive prosperity? The biomedical perspective, *Helen Gubby, Global Policy*, 11 (1) 46-55, WILEY Online Liabrury, <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.
- 20 Annual Report 2022-23, Government of India Ministry of Chemicals and Fertilizers Department of Pharmaceuticals, available at [https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202022-23%20Final-3\\_0.pdf](https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202022-23%20Final-3_0.pdf). Pg.3, (accessed on 11 September 2013).
- 21 “India has 60 percent of global vaccine production, contributing 40 to 70 percent of the who demand for diphtheria, tetanus and pertussis (DPT) and bacillus calmette-guérin (bcg) vaccines, and 90 percent of the who demand for the measles vaccin”.
- 22 *Generic Drug Facts. Fda.gov*. 2018, [cited 12 Apr 2018]. Available from: <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm16799.D>(accessed on 15 September 2013), “A generic drug is a medication created to be the same as an existing approved brand name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics”.
- 23 *Pharmatrac/NPPA/DGCIS, Kolkata*. Annual Report 2022-23, Government of India Ministry of Chemicals and Fertilizers Department of Pharmaceuticals, Available at [https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202022-23%20Final-3\\_0.pdf](https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202022-23%20Final-3_0.pdf). Pg.3 (accessed on 11 September 2013).
- 24 Reddy G B & Kadri A, Local working of patents-Law and implementation in India, *Journal of Intellectual Property Rights*, 18 (2012) 15.
- 25 Vinita Krishna, Sudhir K Jaina & Archana Chugh, commercialization and renewal aspects of patent management in Indian pharmaceutical industry, *Journal of Intellectual Property Rights*, 22 (2017) 211.
- 26 Ghodoosi F, The concept of public policy in law: Revisiting the role of public policy doctrine in the enforcement of private legal arrangements, *Nebraska Law Review*, 94 (2015) 685.
- 27 World Health Organization, Available at <https://www.who.int/india/health-topics/mobile-technology-for-preventing-ncds> (accessed on 23 September 2013).
- 28 Tharkar S, Devarajan A, Kumpatla S, *et al.*, The socioeconomics of diabetes from a developing country: A population based cost of illness study, *Diabetes Research and Clinical Practice*, 89 (3) (2010) 334, <https://doi.org/10.1016/j.diabres.2010.05.009>.
- 29 Singla R, Bindra J, Singla A, *et al.*, Drug prescription patterns and cost analysis of diabetes therapy in India: Audit of an endocrine practice, *Indian Journal of Endocrinology and Metabolism*, 23 (2019) 40.
- 30 Sathishkumar K, Chaturvedi M, Das P, Stephen S & Mathur P, Cancer incidence estimates for 2022 and projection for 2025: Result from National Cancer Registry Programme, India, *Indian Journal of Medical Research*, 156 (4-5) (2022) 598, doi: 10.4103/ijmr.ijmr\_1821\_22. PMID: 36510887; PMCID: PMC10231735.
- 31 Singh P K, Singh L, Dubey R, Singh S & Mehrotra R, Socioeconomic determinants of chronic health diseases among older Indian adults: a nationally representative cross-sectional multilevel study, *BMJ Open*, 2019, 9: e028426, doi: 10.1136/bmjopen-2018-028426.
- 32 The Print, SUMI SUKANYA DUTTA 08 November, 2023 <https://theprint.in/health/at-27-of-global-tb-cases-india-continues-to-carry-highest-burden-shows-latest-who-report/1837738/>. In financial year 2023, a total of over 30 billion Indian rupees was allocated for curtailing and eliminating tuberculosis in India. Whereas the amount spent by the government was over 6.93 billion Indian rupees during the same time period, Tuberculosis elimination program budget and expenditures India FY 2015-2023 Published by A. Minhas, Nov 15, 2023, <https://www.statista.com/statistics/1188932/india-tuberculosis-elimination-program-budget-and-expenditures/>.
- 33 ETHealthWorld Read more at: [https://health.economicstimes.indiatimes.com/news/diagnostics/india-has-a-long-way-to-reach-zero-catastrophic-costs-goal-for-tb-patients-study/97941493#:~:text=%22The%20observations%20were%20disturbing%2C%20as,government%2C%22%20the%20stud](https://health.economicstimes.indiatimes.com/news/diagnostics/india-has-a-long-way-to-reach-zero-catastrophic-costs-goal-for-tb-patients-study/97941493https://health.economicstimes.indiatimes.com/news/diagnostics/india-has-a-long-way-to-reach-zero-catastrophic-costs-goal-for-tb-patients-study/97941493#:~:text=%22The%20observations%20were%20disturbing%2C%20as,government%2C%22%20the%20stud)y%20indicated.
- 34 Locke J, *The Second Treatise of Government* § 27, at 17 (Thomas P. Peardon ed., Liberal Arts Press, Inc. 1952) (1690).A Lockean Theory of Intellectual Property Revisited ADAM D. MOORE Available at <https://digital.sandiego.edu/cgi/viewcontent.cgi?article=1279andcontext=sdlr>.
- 35 Macpherson C. B. (ed), *Second Treaties of Government by John Locke*, Chap 5, Hackett Publishing, 1980.
- 36 Harvard business school online, <https://online.hbs.edu/blog/post/what-is-the-triple-bottom-line>, (accessed on 25 September 2013).
- 37 Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014, 8.
- 38 *Cipla Medpro (PTY) Ltd. v Aventis Pharma SA*, South Africa, Ther SC of Appeal if SA, 26 July 2012.
- 39 India’s poor forced to swallow the bitter pill as medical inflation nibbles at their life savings, *Outlook Business*, Monday, 27 November 2023. <https://www.outlookindia.com/business/india-s-poor-forced-to-swallow-the-bitter-pill-as-medical-inflation-nibbles-at-their-life-savings--news-199526>.
- 40 Ministry of Statistics and Programme Implementation, PER CAPITA INCOME, Posted On: 02 AUG 2023 5:55PM by PIB Delhi, Available at <https://pib.gov.in/PressReleaseFramePage.aspx?PRID=1945144>.
- 41 Inflation Rate in India: November 2023 Data. Edi. By Ashika Jain, Deepen Pradhan. Forbes Staff, Available at <https://www.forbes.com/advisor/in/personal-finance/inflation-rate-in-india/>.
- 42 The Times of India, Business News, Cost of treatment doubles in 5 years as medical inflation bites, Mayur Shetty / TNN / Updated: 23 August 2023, Available at:

- [http://timesofindia.indiatimes.com/articleshow/102961777.cms?from=mdrand&utm\\_source=contentofinterest&utm\\_medium=text&utm\\_campaign=cppst](http://timesofindia.indiatimes.com/articleshow/102961777.cms?from=mdrand&utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst)
- 43 Prinja S, Dixit J, Gupta N, Dhankhar A, Katak A C, Roy P S, Mehra N, Kumar L, Singh A, Malhotra P, Goyal A, Rajsekar K, Krishnamurthy M N & Gupta S, Financial toxicity of cancer treatment in India: Towards closing the cancer care gap, *Front Public Health*, 19 June 2023;11:1065737, doi: 10.3389/fpubh.2023.1065737, PMID: 37404274; PMCID: PMC10316647.
- 44 Government Of India Ministry Of Chemicals and Fertilizers Department Of Pharmaceuticals RAJYA SABHA Unstarred Question No. 1964 To Be Answered On 12th March, 2021; Answer by (SHRI D. v Sadananda Gowda), Reduction in the cost of cancer medicines and drugs “Order S.O. 1041(E) dated 27<sup>th</sup> February, 2019, put a cap on Trade Margin of 42 select non-scheduled anti-cancer medicines under ‘Trade Margin Rationalisation’ Approach. By this approach, the Maximum Retail Price (MRP) of 526 brands of these medicines have been reduced by upto 90%. This move has resulted in annual savings of around Rs. 984 crore to the patients”.
- 45 Chintan R, Increase in drug prices will hit people hard – need for re-orienting drug pricing and production policy (5 April 2022), Retrieved from Newslick: <https://www.newslick.in/Increase-Drug-Prices-Will-Hit-People-Hard-Need-Re-orienting-Drug-Pricing-Production-Policy>.
- 46 *Pfizer Inc. v Cadila Healthcare Ltd* (2020), Proctor v Bennis, 1887, 4 RPC 333; Beecham Group' Limited v Bristol Laboratories Limited (Patent, Interlocutory injunction Ch.D., C.A.) [No. 16] Reports of Patent, Design and Trade Mark Cases] [1967].
- 47 “*Mens Rea is a fundamental concept of criminal law describing that the mental state or intention, commonly called guilty mind, is necessary to commit a crime.*” Mens Rea - A Defendant's Mental State - FindLaw, <https://www.findlaw.com/criminal/criminal-lawbasics/mens-rea-a-defendant-s-mental-state.html>.
- 48 India faced 5,33,295 confirmed deaths during COVID 19 situation, World Health Organization, The current COVID-19 situation, Data reported to WHO in the last 24 hours (accessed on 16 November 2023) <https://www.who.int/countries/ind/>.