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# Critical analysis of the investment protection regime: A proposal by prof. Shamnad Basheer

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**Abstract**
The patent law with respect to the pharmaceutical industries has been under development for a few years now. There are several issues like what should be patented and the duration that have been answered while several questions still have uncertain answers. The aim of this paper is to understand the investment incentive model that Prof. Basheer proposes in his thesis and whether it is a practical solution to some of the questions. For this purpose, the thesis of the author is understood in its entirety before going to the apprehension of the model and linking it to the main objective of the thesis. It also attempts to comprehend the social implications of the model if it is adopted by the nations in today's world. Lastly the paper aims to understand the applicability of the model in the specific context of India by looking at three patent law cases where the decisions might have had an effect if this model was adopted. The paper is a qualitative research that relies on facts and data that have been taken from the thesis itself. It also relies on the facts and circumstances of three Indian cases in order to understand the application of the proposed model in India.

**Keywords:** pharmaceutical firms, patent law, investment protection regime, social implications, India

## Introduction

The thesis, 'The Invention of an Investment Incentive for Pharmaceutical Innovation', by Prof. Shamnad Basheer [1] explains a new investment protecting model that should be introduced in the pharmaceutical industry in order to incentivize the investors to continue high amounts of investment in the R&D process. He tries to introduce such a regime because he believes that the money of the investors should be protected irrespective of whether the drug created is new and inventive which are the two main factors for granting protection under the patent regime. This regime that Prof. Basheer introduced not only attempts to take into account the investment costs during the clinical trial stage but also the costs that were incurred during the drug discovery and development stage.

The difference between this proposed regime and the existing patent and data protection regimes is twofold: firstly, it considers all the stages of drug development, as stated above and secondly, it protects the investors in a proportionate manner i.e. it only allows them to recoup the money that they had invested in the process along with a reasonable rate of interest on that money. This regime can protect the investment along with a reasonable rate of interest only when the profits from that market are only going to the drug originator. Prof. Basheer adds a new dimension to his model by introducing the compensatory liability/licensing model according to which new manufacturers can enter the market after paying a reasonable compensatory amount to the drug originator. This would ensure that the market prices of the drugs are accessible and affordable for the entire targeted audience and the drug originator is not losing out on the profits he/she would have incurred due to entrance of new competition in the market.

The reason he wants to introduce the compensatory liability model are the several shortcomings of the market exclusivity model that he explains while looking at USA and European Union countries that protect the investments in the data generation regime under the latter model. The first shortcoming of such a model is its uniformity with no special provision for the per drug specific investments and its personal health impact. Secondly, it doesn't take into consideration any costs incurred during the stages before the clinical trial stage of the drug in question.

In order to explain his investment protection regime along with the compensatory liability model, Prof. Basheer has chaptered his thesis in order to give a better understanding of his proposed model as well as the reasons behind introducing this new model. It is important to note that he does not propose the stand alone existence of his model; but rather believes that this proposed model can very well work with the existing patent and data protection regime in order to cover the loop holes and flaws of the latter models. There is a possibility that this does not work out in practicality, but he still believes it is worth the chance.

## Focused Arguments of the Thesis

The first chapter of the thesis deals with the various stages of research and development that go into inventing a drug. This helps the readers understand the huge amounts of investments that go not only in the clinical trial stage but also the discovery, development and pre-clinical trial stages which should be

[1] Shamnad Basheer, *The Invention Of An Investment Incentive For Pharmaceutical Innovation*(Law faculty & St Peters College, University of Oxford 2011), Abstract.

recouped by the investors once the drug is launched in the targeted market [2]. The second chapter explains the patent regime in its present form and highlights the several flaws that it has with respect to investment protection [3]. Chapter III attempts to explain the data protection regime, its connection with the patent regime as existing in the USA and the European Union countries [4].

With Chapter IV begins the first proposal of Prof. Basheer's thesis. He starts to explain the investment protection regime which is not uniform in nature but gives market exclusivity to the drug originator for the number of years it would take to recoup the money invested added with a reasonable rate of interest in the invention of that specific drug. This total amount is measured through some metrics such as QALY and DALY. He also states the reason for such a per drug metric i.e. he believes that this would ensure that the investors of that drug are not under-compensated or over-compensated for their investment and risk. This chapter also introduces a compensatory liability model wherein the follow-on competitors are allowed to enter the market and the drug originator does not have market exclusivity. These follow-on competitors have to pay a compensatory amount to the drug originator in order to enter the market of that drug [5]. The next chapter i.e. the fifth chapter only focuses on the practical compatibility of the compensatory licensing model with TRIPS [6].

Chapter VI reiterates the parallel existence of the investment protection regime and the patent regime because although the former regime will function better as a separate regime, there is not a need to reduce the patent threshold. The investors can be protected through the investment protection regime while the product and the process of development can be protected by the existing patent regime. While Prof. Basheer appreciates the fact that in light of TRIPS and significantly accelerated innovations, it would be nearly impossible to dismantle the patent regime, he argues that there could be a possibility wherein the data protection regime could be dispensed with. He makes this argument because he believes that the data protection regime only protected the investment during the clinical trial stage while his investment protection regime protects the investment during all the stages involved in development of a drug [7].

Chapter VII attempts to understand the global practicality of the proposed regime. The author of this thesis understands that while the developing countries will be in the favor of promoting market exclusivity regime in their country in order to protect the patients' interests and public health, the countries that already have the patent and data protection regimes could be convinced to give this proposed regime a trial [8]. Finally, the last chapter of the thesis attempts to give alternative incentives for the pharmaceutical innovations and the difference of treatment of a specific drug in the developing and dev eloped countries. This chapter also concludes the entire thesis by reiterating the most important proposals and key arguments [9].

**Objectives and Methodology of the Study**

The aim of this paper is to critically analyze the proposed investment protection regime as a whole and in specific context to the Indian Patent Law. In order to achieve this objective, I will be understanding and summarizing the purpose and arguments of the entire thesis written by Prof. Basheer. Furthermore, I also try to understand and summarize his investment protection regime and link it back to the main thesis arguments in order to comprehend the relevance of the same. The paper is a qualitative research that relies on facts and data related to the data protection, patent and investment protection regime that have been taken from the thesis itself. It also relies on the facts and circumstances of three Indian patent law cases in order to understand the application of the proposed model in India.

**Investment Protection Regime [10]**

The central theme of the thesis in question is that the research and development department of the pharmaceutical industry along with the innovation and launch of the new drug can only function and expand if the investors are continuously motivated to invest in the process. According to Basheer (2011), that is not being achieved by the existing patent and data protection regimes for the reasons stated in the first part of this paper. Therefore, the investment protection regime is proposed. There are two main requirements for the effective practice of this proposed model. Firstly, the drug originators are required to submit all the costs that are related to the discovery and development stage of the drug. Secondly, the drug originator is granted market protection until he recovers all of his costs and depending on the health of the drug, a reasonable rate of interest on those costs as well.

In order to make this a practical model, there are two versions of it that have been proposed by the author. The first model is market exclusivity for the drug originator wherein until and unless all the costs as well as the reasonable rate of interest for the drug originator is not recovered, there can be no competition selling that drug in the market. The second model is the compensatory liability or compulsory licensing model wherein a new competitor can enter the market but only after paying the drug originator a reasonable amount of compensation for the distribution or manufacturing or production of that drug. I agree with Basheer that the compulsory licensing model is a better model for the effective working of the investment protection regime model because the prices of the drug will not be sky rocketing owing to the single competitor in that drug market.

The next segment of this model is to understand which costs of the drug originator should be included in the report that would be submitted to compute the compensation as well as the reasonable rate of interest. The principle behind computing these costs is to analyze them per individual drug rather than on a wide spectrum of drugs (DiMasi and others' model [11]) as it is an easier endeavor. There are three main costs that should be included-

1. All the expenses that were incurred during and in relation to the drug in the discovery and development phase which were upheld by the drug originator.

[2] Ibid., Chapter I, 37-45
[3] Ibid., Chapter II, 50-97
[4] Ibid., Chapter III, 100-115.
[5] Ibid., Chapter IV, 121-187
[6] Ibid., Chapter V, 195-214.
[7] Ibid., Chapter VI, 217-234.
[8] Ibid, Chapter VII, 242-253.
[9] Ibid, Chapter VIII, 257-296.
[10] Ibid, Chapter IV, 121-129.
[11] Joseph A. DiMasi *et al., The Price of Innovation: New Estimates of Drug Development Costs*, 22(2) JOURNAL OF HEALTH ECONOMICS 151, 165 (2003).

2. If the manufacturing facility for that drug has been solely created for the purpose of manufacturing that drug, then all the fixed costs related to setting up this facility.
3. All the costs of the tried and tested leads and targets that are in relation to a particular league.

In order to make the readers understand what is included in the discovery and development stages of the drug, Basheer gives an example of the drug Glivec, an anti-cancer drug, thereby explaining the various stages involved in the manufacturing of that drug and what stage would start to be included in the costs accrued in the creation of the same.

Apart from the three costs mentioned above, the fourth very important cost comes into play when a particular drug has failed to get the approval of the drug regulator. This cost is called the cost of failure. There are several occasions wherein the drug originator is unable to meet the regulatory standards due to which the investors lose their money as there are no profits from which they can be paid back. Basheer proposes that the investors of such failed attempts should also be protected by including these costs so that their motivation to invest remains high and they restart the process in order to make the drug a success.

Lastly, on the topic of drugs, there are two costs that should specifically be excluded while the reports are being submitted. The first cost is the cost that the drug originator incurred while creating a second derivative drug when the costs of the first drug from which the former was created has already been claimed. Secondly, if the drug originator has received any public funds for the creation and research and development of the drug, such amounts should be reduced from the total costs incurred report.

The last segment of this regime is to understand how to compute the amount of money that has already been compensated to the drug originator and the investors. The first requirement would be to submit annual revenues and profit reports. This would ensure the accurate computation of money that is being received year after year by the drug originator till the time the entire investment along with a reasonable rate of interest is compensated to him. Once the yearly profit returns of the pharmaceutical firm give a prima facie opinion that the compensation of the costs is near, the firm or the drug originator should start submitting a monthly profit report. This period would now give the chance to a new manufacturer who wants to enter the market for that drug to file an application for regulatory approval which will not be denied if all the standards are met. The new manufacturer, however, will be restricted from entering the market till the drug originator has been compensated for all the investment and a reasonable rate of return.

This regime connects back to the entire thesis of the author in the sense that the author believes that the patent and data protection regime existing in the world are not enough to protect or motivate the existing pharmaceutical firms and the drug originators as well as the investors to continue investing their hard work and money into the creation of drugs for betterment of the society. This regime is the central theme of the thesis and therefore extremely important to understand because unless there is a basic understanding of this model, the readers would be unable to understand its purpose or its advantages.

**Analysis of the Investment Protection Regime: Commercial, Legal, Ethical and Social Implications**

This part of the paper is an objective analysis of the proposed model i.e. investment protection regime that I, attempt as a reader of the same. The proposed model is still a theoretical model that is yet to be practically implemented by any of the nations, however, the great amount of work that Basheer has done in the field of intellectual property rights gives his thesis great credibility.

There could be several positive and negative social implications [12] of this regime if it is adopted as a practical model as a whole for all its intents and purposes.

1. Commercial Implications: The positive implication would be that more investors who are as of now scared to invest in this risky pharmaceutical industry would be motivated to at least give it a thought because they will have the safety net of being compensated for their investment even if there is a failure. Secondly, the prices of the drugs being created for the purpose of curing diseases would be minimal because the companies would not have to worry about recompensating themselves for their investment as soon as possible and the drugs could become easily accessible to even the lower strata of the society. The negative implication, however, could be that in a case where the development of the drug involved huge investments, the drug originator would have market exclusivity for a long period of time in order to be compensated and there is a possibility that the industry might hike prices to speed up this process.
2. Legal Implications: The positive legal implication of this regime would be that the concerned regulators and authorities will not only have the costs incurred by a pharmaceutical firm to create a drug, they would also have the annual profit and revenue reports of these firms when the drug would enter the market. This would ensure transparency between the authorities and the firm creating a stronger and better method of regulation. Furthermore, the investors will have a legal remedy to rely on if their money is not being fairly recompensated by the pharmaceutical firm in an orderly manner. However, owing to the greed, which is a general trait of humans, there is a possibility of fabrication of costs or profits and revenues report in order to increase the compensation amount and the reasonable rate of interest that is owed to such pharmaceutical firms.
3. Ethical Implications: Since the pharmaceutical firms will have to submit their cost reports even for their discovery and development stage in order to claim compensation, it would ensure that the firms strictly adhere to all the legal requirements for the creation of a drug. If there is any anomality in the cost reports submitted, the pharmaceutical firm might face consequences.
4. Social Implications: The purpose of creating pharmaceutical drugs is to ensure maximum cures available in the society for

[12] *Mapping And Sequencing The Human Genome* (National Academies Press 1988), 99-100.

> The diseases and epidemics that couldn't be cured before. A disease does not see the social, economic or cultural background of the person, rather just affects the person. Adopting this model would be a step towards ensuring that maximum people including the socially, economically and culturally marginalized people have access to the drug as the prices would not be unreasonably set. The prices of a drug are high because the drug originator wants to recollect the money as soon as possible. If the investors of the drug originator are guaranteed compensation under this model, the reason for hiking prices ceases to exist.

Every coin has two sides and therefore every model will have its pros and cons. The question therefore becomes whether the positives outweigh the negatives in order to make it a practically working and efficient model. In my opinion, this model has several positives that would enhance the existing patent law across the nations and protect and regulate the pharmaceutical industry in a much better way. I did not include the data protection regime of the pharmaceutical industry in the above equation because this model gives a better safety net to the investors as well as the data of the pharmaceuticals and hence, I agree with Basheer that the former model could become redundant if this model is adopted.

**Application of Investment Protection Regime in India: A Potentially Beneficial Move?**

The first Patents Act in India came in 1970. Under this Act, only process patents were allowed, and no specific product was allowed to be patented. This was a huge issue for the pharmaceutical industry because although the process of creation of their drug could be patented, their drug couldn't be [13]. Therefore, if a competitor found a different process to manufacture the same drug, there would be nothing under this Act that the drug originator could rely on. This law changed in 2005, when an amendment was made to the patent law allowing product patents as well. This new law had three main criteria that had to be satisfied in order to obtain a product patent, namely the product had to be new, innovative and should have industrial applicability. The Act, in some sense, has adopted this model via the compulsory licensing model. Under Chapter XVI of the Patent Act, 2005, the government can authorize an organization other than the patent owner of the drug to manufacture the same drug in the market [14].

Since this law is relatively new, there are several court judgments that give nuances to this law through their interpretative power where the investment protection regime would have created better situations. The first case that will be discussed is *Novartis v. Union of India* [15]. The Supreme Court denied a patent to the applicants because the drug did not meet the innovative criteria. The case became a landmark judgment because the it looked beyond the law and tried to curb the attempt of the applicants to dominate the prices of the drug in the market. If India adopts the investment protection regime, the situation where a pharmaceutical firm would attempt to dominate the prices would not arise because as explained above, the investors and the drug originator would have a legal safety net that their investment will be compensated along with a reasonable rate of interest. Furthermore, a pharmaceutical firm would never be able to claim compensation for a second derivative of the drug because such costs would be explicitly excluded from the computation of costs process.

The second case where this model becomes relevant *F.Hoffmann-La Roche Ltd. v. Cipla Ltd* [16]. In this case the main issues were patent infringement by Cipla and the price domination by Roche. Cipla's product which had allegedly infringed the patent was priced at a third of the drug by Roche. In such a scenario, the courts were conflicted between patent infringement and public interest because the entire purpose of the pharmaceutical industry is to create accessible drugs and not maximize profits. Applying the investment protection regime, the same reasoning as from the first case flows which is that the compulsory licensing model would allow the prices to be affordable through introduction of new manufacturers in the market along with protecting the investment of the drug originator in creating the drug.

The last case that is being discussed is *Bayer Corporation v. Union of India* [17] This was the first case where the Indian Patent Office granted a compulsory license to a pharmaceutical firm apart from the drug originator. The main issue in this case was the interpretation of the process of granting compulsory licenses. There were several legal terms and norms that were looked at by the High Court to give the decision and when the matter was appealed to the Supreme Court, the court left all the legal questions open-ended. This means that there is still no settled law in the country with respect to the process of granting compulsory licenses. The adoption of the investment protection regime model would ensure a basic legal framework that needs to be adopted in order to ensure that the process is smooth and effective. The legal questions, then related to the process wouldn't be left open ended as their will be a stringent process as a law in place.

**Conclusion**

The purpose of the thesis written by Basheer was to propose a new investment incentive model that would tie all the loopholes in the existing patent and data protection regime. This model has certain negative social implications but as I have argued above, they have been overweighed by the positives and therefore it is a model the nations should give a thought about. Lastly, taking the Indian scenario into consideration, the model will be a great asset to the intellectual property law because it will answer several questions that have uncertainty attached to them even though the

[13] Vipin Mathur, 'Patenting Of Pharmaceuticals: An Indian Perspective' (*Ijddr.in*, 2019) <http://www.ijddr.in/drug-development/patenting-of-pharmaceuticals-an-indian-perspective.php?aid=4994> accessed 15 September 2019.

[14] 'Indialaw LLP Blog' (*IndiaLaw LLP Blog*, 2015) <https://www.indialaw.in/blog/blog/intellectual-property-rights/bayer-corp-v-union-of-india/> accessed 15 September 2019.

[15] (2013) 6 SCC 1.

[16] CS (OS) No.89/2008 and C.C. 52/2008.

[17] Special Leave to Appeal (C) NO(S). 30145/2014.

matters have been heard by the courts.

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