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Rethinking The Need For Defining 'Efficacy' In The Indian Patent Regime

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ABSTRACT

The verdict of the Novartis AG v. Union of India provided a big sigh of relief to the poor section of people as it eased them to afford to critical life saving drugs. This however, if looked at the standpoint of the corporations attempting to patent new drugs and models based on incremental inventions, the Judgment could add a lot of burden on their part to arriving at an increment and may deter their progress in the field of inventions because the Indian Patent Regime in Section 3(d) of the Indian Patent Act, 1970 does not define what Efficacy is. For this, the proviso is analyzed in depth and attempted to understand the secondary meaning it could convey.

The non-definition of efficacy and the drug manufacturers being put under the question of 'what is an increment/efficiency?' creates a gray area in the parameters of determining efficiency and solely vests the power to determine with the Patent General and the Courts. This paper analyses on the decision of Bayer and subsequently Novartis in an aspect that has neither been expressly explained in any theoretical writings on this issue, nor the referring judgments itself. The act of 'evergreening' attempted by the Corporations to extend their patents but as another documented shortcut is also highlighted.

This paper, 'rethinks' into the possibilities and predicts the pretext on account of the verdict as how the same would have created a positive impact in the Indian population and maybe, why that could have been the reason behind the Judgment itself in the first place.

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TABLE OF CONTENT

I. INTRODUCTION

'Efficacy' is an instrumental concept under Section 3(d) of the Indian Patents Act, 1970. It directly determines the patentability and also indirectly affects a few other provisions under some related regimes, e.g. Drugs (Control) Act, etc. Especially applicable to incremental innovations, the 'efficacy' factor forms the sub-stratum of tests (of patent-eligibility and Patentability) under Section 3(d). The criticality of the Efficacy factor can be gauged from Mueller's observation that the presence of this section renders the new Indian Patent Regime neither a 'Westernized Remedy' nor an 'unmitigated disaster for the Indian Public'

The paper takes a holistic approach to reason out the factors that the Court could have considered but not explicitly expressed behind the rationale of such a Judgement, presented in the views and the opinions of the authors.

II. SECTION 3(d) OF THE PATENTS ACT

3. What are not inventions. — (d) – *"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation -For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy"*

III. UNDERSTANDING SECTION 3(d)

On the careful reading of the entire provision, one thing becomes evident; this section disallows any new substance or invention that has been applied for patent, which is a mere improvement or development of any granted patent that is already existing in the market or has been duly used by the granted patent applicant. It is pertinent to understand with the given inclusion of certain substances of salts, ethers, esters etc., we can arrive at an inference that the prime concentration of this provision targets pharmaceutical drugs and drug related patent applications. To

understand why these criteria have been specifically formulated into this section, it is imperative to trace its history.

IV. HISTORY

Section 3(d) was added only in the year 2005, vide The Patent (Amendment) Act, 2005. Until the addition of this provision, barring granting patents for mere improvements of known substances, any kind or subjects of technology consisting of drugs, chemicals, food and micro-organism-related applications were granted patents. There were hardly any strict regulations regarding such criteria to decide whether an application is genuine or not and whether the substance differs from any known substance or not.

V. WHAT IS A KNOWN SUBSTANCE?

A known substance is any patent held by any individual or a company whose patent tenure is still active and is duly registered and authorized by the Controller.

VI. HOW TO DIFFERENCIATE FROM A KNOWN SUBSTANCE?

As it is a decided rule that any new products that attempt to secure a patent cannot be a mere development or a mere discovery of a new form of a known substance, the only criteria that is required by the Patent Controller for new inventions is that the patent applicant show "efficacy" or in common parlance, 'efficiency' in their product to signify and prove that their invention is more advanced and not a simple improvement over the composition of a known or already-patented substance.

VII. DIFFICULTY IN THE EXPLANATION OF WHAT IS EFFICACY

'Efficiency' to be simply defined is something that proves significant change in the compositional or structural integrity of such substance or the result that it will yield, from the known substance or already-patented subject.

However, the difficulty arises, when the question of defining 'efficiency' or 'efficacy' arises. The Indian Patent Regime has nowhere defined 'efficiency' or 'efficacy'. The term 'efficacy' is simply put in the Section 3(d). However, that is the sole strong criterion to verify any new application attempting for a grant of a patent and to prove a solid difference between it and a known substance proves to be challenging due to the lack of a clear-cut definition.

VIII. THE NOVARTIS CASE

In the famous Novartis Case[1], a Sweden based company applied for a patent before the Chennai Patent Office for their drug named 'GLIVEC' which was their invention to counter the cancer cells which was the mere improved version of their own Anti-Leukaemia Drug in terms of chemical components and composition. The Assistant Controller Patent rejected the application citing Section 3(d), stating that the said application had failed to prove any efficacy and generate a much-improved position from any known substance. However, the Anti-Leukaemia drug was granted the patent with the same company. The new drug 'GLIVEC' was, however, rejected. The case was a long drawn out battle at the Madras High Court and was finally given the verdict in 2013.

Novartis challenged the entire provision stating that it was in direct contravention to the TRIPS Agreement and more importantly, it is not valid to reject their application on the grounds that there was a lack of proving 'efficacy' of the drug when the term efficacy itself is not expressly defined. Therefore, not having an explicit definition for 'efficacy' would mean that the entire power and authority to decide and determine what efficacy is would completely vest on the respective Patent Controller or their delegator, which was arbitrary in nature.

The Madras High Court observed that if it comes to the test of efficiency or 'efficacy' in the field of the medicine, then it must be only therapeutic efficacy, which in simple words, would mean that the products' effect of the application on the targeted persons would show any significant form of improvement in therapy providing a remedy to such an ailment or heal the intended infection.

Finally, the Court did not award the decision in favour of Novartis, thus benefitting the Indian society to have unfettered access to generic medicines at affordable rates and prevent big

[1] Novartis AG & Ors. .v. Union of India & Ors. AIR 2013 SC 1311.

pharma companies to patent such medicines and sell at high costs, thus causing a restriction of access of such drugs to many ailing people.

IX. CRITICAL ANALYSIS

This entire section is an expression of what the researchers have perceived after thorough research on the battle to define 'efficacy' between the Pharma Companies and the High Court's or the Government's defiance to do the same. As the researchers has observed the design, implementation and the process of how Section 3(d) is handled both by the Controller of the Patent in determining new applications as well as the way in which the High Courts have handled such cases that have come before them on appeal, comprehend and deduce to the understanding that despite many disparagements and criticisms arising against the validity of Section 3(d) by various multinational Pharma Companies or other Governments backing their freedom to trade under Article 19(1)(g) or backing what was held in the TRIPS Agreement, to which, India was a signatory of, on the grounds of specific guidelines issued for determining incremental innovation and the TRIPS' guidelines asking its signatories to not go with stricter requirements for obtaining the patent against what the TRIPS agreement has given. The same was also put forth as a challenge by the Novartis in the Madras High Court Case.

Not just the present pharma companies that exist in India oppose Section 3(d), but also the United States of America's Government vide its Special 301 report dated 30th April, 2014 classified India as a "Priority Watch List Country". The Indian Ministry of Commerce and Industry defended the Indian Patent Regime stating that due to the nature of Section 3(d), disallowing evergreening of patents, has been a cause for concern to the US Pharma Companies[2] (which indirectly hinted that the US Government, to subtly promote the US based pharma companies in other Countries, gave out such a Special Report).

But the ultimate question that arises is "Why the Indian Government and the Courts of India are trying so hard to defend Section 3(d) without defining the term 'efficacy' to simplify the patent process.

To understand this, we must first understand the other challenges arising as a result of the non-definition of the term 'efficacy'.

[2] https://pib.gov.in/newsite/printrelease.aspx?relid=107612 (Last Accessed on 04.11.2019).

Efficiency is the key and sole factor for any new patent application to overcome Section 3(d)'s requirement and get approved to be a patent by the Controller of Patent in India.

There are certain measures that the Pharma Companies resort to, to extend their patent applications. The underlying reasoning is that they would be able to make more money and procure rights over their products. The longer such rights stay with them, the more money they are going to make as a result of the exclusivity of such products, as the time frame to hold a patent is only 20 years in India. If a company makes a lot of profit out of such a patent, it is reasonable to draw he inference that the companies would like to extend the profits and thereby aim to extend the duration of the patent through one way or another.

This is where the big companies might adopt the practice of finding another new invention or improvement to the existing substance and thereby, attempt to patent the same which, in essence, would help them retain the same benefits as the older patent, legally, having a new application at hand. To succeed in this, the companies would formulate new inventions that are based on the already-granted patent and show significant improvements over the old ones to contrast and differentiate the new application as a brand-new invention.

This is where the Madras High Court in the Novartis case ruled that 'therapeutic efficacy' is essential for the grant of patent by the Controller of Patent. The therapeutic efficiency would be the final criteria for the new invention. This proves to be a contrast to the older patented inventions when the effect of the application of the medicine is proven in the medicine's outcome to heal.

Thus, it is extremely difficult for the companies to show the same final output for a new medicine or a new drug while having almost similar base compositions with an existing patent application. This almost voids them from obtaining the Patent. Thus, by way of indirect application of the term 'therapeutic efficacy', the Indian Patent Regime has denied the concept of evergreening of patents.

Another challenge is the Patent Linkage that the companies engage to battle and take advantage of, against the Indian Patent Regime. To understand Patent Linkage, we need to understand the two types of manufacturers namely, the

i. The Original Manufacturer – The one who originally invents and gets granted of the patent.

ii. The Generic Manufacturer – The one who produces the same patented invention in their facility to exactly demonstrate the same, right from the base compounds to the final outcome of the effect of application of such a patented product.

Patent Linkage in simple words refers to the duty of the Patent Office of India and other National Level Authorities to prevent any form of approval of such generic companies with their products whilst the patent of the original manufacturers is still valid, that is, the 20 years tenure has not ended yet. Most commonly, the generic drugs are much cheaper and are widely available for access to the common public than the comparatively expensive and dealership based original manufacturers' products.

The reason why the companies continue their fight for India to validate patent linkage in India is because, they think the generic manufacturers would not commit to the highest quality of the drugs or components used to manufacture such goods, and if any one mishap happens with the generic manufacturers' products, their company would also suffer in the people's perception.

Another challenge is that of data exclusivity. It is a rule for the Patent Applicants to present and submit all the methods undergone in the process of manufacturing a said pharmaceutical drug that includes the data from the tests (both failed and succeeded) and the revision of successful tests using various trial and error data. These compilations of the data have to be submitted to the Indian Patent Office and the same will be published in the Journals as well to be available to the public.

Now the difficulty arises when there are other illegal or small level manufacturers or other manufacturers who would take this data available for the public, and generate and invent their own version of the drug to use it as a cheaper alternative of an existing expensive medicine, or invent some other drug based on the ideas gathered from the successful tests of the patented invention, and attempt to claim for a patent for the new invention.

The only hurdle for the new manufacturers would be to cross the 'efficacy' test and if they manage to show and prove therapeutic efficacy, then they would be granted the patent no matter where they gathered their primary data and the idea for the invention from.

The Bayer Case [3] discussed all of the above and affirmed that India does not have the patent linkage regulation. The Court also held that Section 122E of the Drugs and Cosmetics Rules, 1945 provided relief to certain extent for the original manufacturer to keep the data in private for

[3] Bayer Corporation and Others v Cipla, Union of India (UOI) and Others, 2009 (41) PTC 634 (DEL).

a maximum of 4 years from the date of granting of the patent. Further the Delhi High Court also opined that if the case were to be awarded to Bayer, then it would legally mean and deem that all the products manufactured by the generic manufacturers would have to be forcefully called as "spurious drug" or in other words, false drug.

Of all these, what the researcher has deduced to the point of understanding, is that the Government or the Courts of India has left the term 'efficacy' from defining not because of lack of knowledge or to abstain from the pressure from the Big Pharma Companies.

Reading aforesaid scenario would reveal to the researcher that India is concerned about holding the provisions signed in the TRIPS Agreement to which, many other big countries are a signatory of, which include the Capitalist-centric countries as well, where, money is the prime player of every action or decision.

In a country like India where over 85 percent of people fall under the Below Poverty Line, the urgent need when an endemic disease spreads or to generally keep the health ratio of the people healthy, is to make available the drugs for such people at a cost that they could afford. The Government of India cannot indulge in any direct involvements to bring such drugs at affordable rates which will demand it to act in contravention of the TRIPS Agreement, but what the Government can do is that it can engage in drafting its policies while the Courts can issue suitable decisions in such a way, both which would maximize the benefit for the common people or the public at large. To keep the subjects of a country healthy, is the first sign of development, and India, given its position economically, has to overcome its challenge, rather not, make it complex.

Defining 'efficacy' would give rise to many further complexions at small and larger level and would result in clashing of many issues at one go, which will eventually cloud more difficulties. However, the public who are the consumers of the end product of these patents will again be the ultimate victims to these confusions. Therefore, refraining from precisely defining 'efficacy' would comparatively lead to lesser confusions and would also enable a case-to-case examination by vesting all the power to determine what would be efficacy, to the Controller of the Patent.

It is rather a battle of an ethical dilemma that the Government and the Courts of India have resorted, to save the public's larger interests in the best way possible and also, to satisfy their position of obligation to serve the public, in the best manner.

The researcher while observing all of these appreciates the Government and the Courts for handling this issue, this way, if everything is deemed right according to his observations.