An Attempt at Quantification of 'Efficacy' Factors under Section 3(d) of the Indian Patents Act

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This policy paper attempts to develop a very simplistic theoretical model for helping patent authorities determine the patentability / patent-eligibility of a pharmaceutical invention. Though yet to be empirically tested, the proposed model (based on the wider interpretation of 'efficacy') may serve a very useful guideline, thereby lessening the arbitrariness and uncertainty in the application of the 'efficacy' standard under Section 3(d). This model has been proposed as part of a comprehensive reform in the extant patents regime in India. However, this domestic level reform has to be matched by a concomitant reform at the international level.

Keywords: Section 3(d), therapeutic, law & economics, pharmaceuticals, patentability, patent eligibility, transaction cost, externality, innovation, Efficacy Matrix, Pareto, TRIPS, petty patent, technology transfer, market failure, expressive function of law, choice architecture, policy levers, law-in-books, law-in-motion, burden of proof

'Efficacy' is a pivotal concept under Section 3(d) of the Indian Patents Act, 1970. It directly determines 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 the Section 3(d). The criticality/centrality of the 'efficacy' factor can be gauged from Mueller's[1] observation that the presence of this section renders the new Indian patent regime neither a 'Westernized panacea', nor an 'unmitigated disaster for the Indian public'.

Proposed Hypothesis

The Problem

The concept of 'efficacy' has not been concretely defined under any patent regime of the world. This undefined status leaves discretion in its application in the hands of the patent authorities, which results in misapplication, arbitrariness, legal uncertainty and corruption, all of which have are welfare-reducing.

The Solution

To redress the above-mentioned problem, it is proposed that some legal-institutional reforms, especially the application of the current author's Efficacy Matrix (based on the wider interpretation of 'efficacy') and threshold/cut-off for patentability of pharmaceutical products under Section 3(d), shall bring in legal certainty, thereby making it Pareto-superior.

Motivation

The need (1) to increase the innovation-rate, in order (2) to transform the Indian pharmaceutical industry's generics-orientation to innovation-orientation, (3) the social cost imposed by (4) the imbalanced incentive-structure under the current patent regime and (5) the absence of any integrated doctrinal approach, are the prime motivators for the current attempt at developing a simplistic model for 'efficacy' under Section 3(d). One of the very few comprehensive legal analyses[2,3] of the subject has been done by Basheer[4], where the author himself admits that their mere legal analysis requires a detailed empirical and policy analyses. The current paper attempts to fill this gap by analysing it from the policy perspective only, while the empirical analysis has been left for future research.

Scope & Limitation

The following aspects simultaneously constitute the scope as well as the limitations of this research

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paper. However, they also contain the seeds of future research.

This paper belongs to the realm of policy research, the scope of which is defined and limited by the following two paramount research concerns:

(1) What is the need for defining the concept of 'efficacy'? and
(2) How more certainty can be imparted to the concept of 'efficacy'?

The first question logically leads to the analysis of various reasons for clarifying the concept of 'efficacy'. These reasons naturally demand reforms, which led the current author to undertake the development of an efficacy testing model for uncertainty-reduction.

A limitation of scope of this research is that it is confined to the examination of 'efficacy' (which includes 'enhanced efficacy') within the boundaries of Section 3(d) under the Indian Patents Act. This enquiry is further limited in scope to pharmaceuticals only.

This hypothesis is purely theoretical and needs to be empirically validated. This is not easy because (1) the sheer enormity of the involved data at USPTO, EPO, JPO itself is a big deterrent to undertake an exercise of identification of the relevant 'efficacy' factors and (2) even though the amount of data at the IPO is relatively not so huge (because the pharmaceutical product patenting began only in 2005), yet the accessibility to the Indian data is a big issue thereat.

Assignment of weights to the identified relevant 'efficacy' factors is another limitation. The proposed method of weights-assignment may be criticized to be an inappropriate proxy. But it must be appreciated that since the concept of 'efficacy' has neither anywhere been defined (in pharmaceutical patenting), nor is even capable of being defined with precision, one can only make approximations of the weightages to be assigned to the relevant 'efficacy' factors. The historical experience of the various patent offices will yield many relevant factors of 'efficacy' and the frequency with which those factors have been used in granting (or refusing) patents, might be good proxies for weights-assignment, as they indicate some probability of occurrence. In the absence of any other option, this probabilistic weights-assignment may be a reasonable proxy. However, its causal relationship has yet to be established through an empirical analysis, which is beyond the scope of the present research.

Another limitation is that it seeks to achieve mere Pareto-superiority, and not Pareto-optimality, because there is no pharmaceutical patent regime which can optimally/efficiently distribute the incentives/gains among its stakeholders.[5] Pareto-optimality is a state whereby no one can be made better off without making anyone worse off anymore.[6] Pareto-superiority is only a better state compared to some other non-Pareto optimal state.

Legal Analysis
Brief Legal Historical Background on 'Efficacy'
The pre-independence period was marked by the British patents law. In the post-independence era, the first major change therein was brought by the Indian Patents Act (IPA), 1970 whose Section 5 disallowed the hitherto allowed product patent in pharmaceuticals[7] and thereby facilitated the subsequent booming of the Indian generics industry.[8] Since pharmaceutical product patenting was disallowed, the 'efficacy' factor hardly had any role to play. The next major amendment came in 2005, when in order to be TRIPS-compliant, India reintroduced pharmaceutical product patenting by deleting Section 5 and introducing Section 3(d), whose rationale was the need to check the practice of 'evergreening'[9,10] and 'product hopping'.[11] It certainly was not meant to disallow patenting of all incremental innovations.[12] However, the strict enforcement of this provision by the Indian patent authorities, coupled with the narrow interpretation (by the courts) of the term 'efficacy' as merely 'therapeutic efficacy', has led some interest groups to allege that the new standard is designed to disallow patenting of all incremental innovations.

Issues Directly related to 'Efficacy'
Ever since the 2005 amendment, in the explanation to Section 3(d), the 'enhanced efficacy' factor has become critical for incremental innovation (selection patents). India used the flexibilities granted under the TRIPS Agreement to introduce this hitherto unheard of provision.

The TRIPS Agreement[13]
Article 27.1 of the TRIPS, provides for the availability of patents for all products/processes without discrimination, provided they satisfy the three patentability criteria of novelty, inventive step and utility. The Articles 27.2 and 27.3 provide for exceptions and flexibilities for deviation from the patent-eligibility criteria. The term 'patent-eligibility'

relates to all inventions that have been specified by the TRIPS and the national Acts to be eligible for getting a patent, subject to exceptions. If the patent eligible inventions can also actually satisfy the prescribed national standards of novelty, non-obviousness and utility, then they become 'patentable'. A patent-eligible subject-matter may not be patentable and a patentable subject-matter may not be patent-eligible. Its vice versa is also true. The current international controversy over 'efficacy' *vis-à-vis* India, is less about patent-eligibility and more about patentability. Also, it is more about 'enhanced efficacy', than about 'efficacy'. Unfortunately, the IPA, 1970 merges these two concepts of 'patent-eligible' and 'patentable' and uses them interchangeably/confusingly.

The research findings on the impact of TRIPS are inconclusive. While either confirming or contradicting its beneficial effect, studies largely reflect the North[14] *vs* South[15,16] interest-alignment. Correa's[17] compendium of patentability strategies for the developing countries is an example of the Southern advocacy. Chaudhuri[18], doubts even the need for product patenting in India. Scotchmer[19] holds that second generation product patents are not necessary for their (i.e. the second generation products') innovation. Lanjouw[20] sees its negative impact on the public. One traditional trade law school holds that the increased legalization of the world trade regime ultimately benefits the economically weaker countries in the long-term.[21]

Without any partisan side-taking, the current author is of the view that India must give due weightage to the innovation-promoting role of patent monopoly under certain circumstances, especially under a level-playing field. On the other hand, the TRIPS-plus votaries also must recognize that Indian patent regime is totally TRIPS-compliant[3] and even its 'enhanced efficacy' requirement under Section 3(d) has been enacted using the flexibilities (both, procedural and substantial) allowed under the TRIPS and, hence, legally there is no TRIPS' non-compliance on the part of India.[22] But, even this technicality is not the real concern. Far more important is the Pareto-superiority (or inferiority) and the net welfare effect of this provision. Since the current incentive-structure is clearly lop-sided, a distributive exercise at both levels, domestic and international, is required. But, this distributive exercise involves the understanding of its legal nuances.

Section 3(d)

Although the patent regimes are territorial[23], yet the re-introduction of pharmaceutical product patenting in India opened the Pandora's box at the international level. Section 3(d), which puts a restriction on such patents, reads as follows:

> Section 3. What are not inventions
> The following are not inventions within the meaning of this Act,—
> (a)…(b)…(c)…
> (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

Breaking it down into smaller constituents[24], one gets the following:

Main Section:
- mere discovery
  - of a new form of a known substance
  - not resulting in 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 process results in a new product or employs at least one new reactant

Explanation:
- 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

The 'efficacy' factor is crucial here. The main Section requires the 'enhancement of the known efficacy', while the Explanation requires the derivatives to 'differ significantly in properties with regard to efficacy'. The standard of proof regarding efficacy in the former case is lower than that in the latter, where it becomes even more complex because of the uncertainty regarding what quantum of 'enhanced efficacy' would be considered as 'significant'. Moreover, the latter requirement is not about 'efficacy' *per se*, but about the properties regarding efficacy. Thus, it becomes even more important that the relevant efficacy-factors (identified by the author later in this paper) must be given due weightage and wider interpretation while examining 'efficacy'.

Definitions of 'Efficacy'

No patent regime has ever concretely defined 'efficacy' in the context of pharmaceutical patenting. Further uncertainty is created by the use of various similar terms[25], e.g. 'effectiveness', 'relative efficacy', 'comparative effectiveness research', 'efficiency', 'added therapeutic value', etc. Also, there is a difference in the sense in which different authorities use the term 'efficacy', depending upon whether one is a patenting authority, or a drug regulatory authority, or a third party payer, or the general public. Moreover, the Indian patent authorities use the terms 'efficacy' and 'effectiveness' interchangeably. The word 'effectiveness' is actually a wider term and 'efficacy' may be interpreted as a special case of 'effectiveness' itself. Even when the Indian authorities mostly use the word 'efficacy', they essentially perform the 'effectiveness' analysis. The comparison of efficacies of the new drug with prior art and/or other drug makes it an effectiveness examination (which is relative), rather than an efficacy examination (which is absolute). The confusion is further compounded by the Indian courts who fail to fulfill their clarificatory function by narrowly interpreting 'efficacy' as mere 'therapeutic efficacy'.[26]

The dictionary definition: The Oxford English Dictionary broadly defines 'efficacy' as 'power or capacity to produce effects'.[4]

The Novartis case (2007): On the basis of Dorland's Medical Dictionary definition of 'efficacy' in the field of pharmacology, the court interpreted 'efficacy' as 'the ability of a drug to produce the desired therapeutic effect' and 'therapeutic' as 'healing of disease', i.e. having a good effect on the body.[4]

As per Ohly[3], narrowly limiting 'efficacy' to mere 'therapeutic efficacy' is against the legislative intent. It fails to take various aspects, viz. bio-availability, toxicity, heat stability, new drug delivery mechanisms, etc., into account. This narrow interpretation is based on many wrong assumptions - that Section 3(d) is limited to drugs only; that it applies to humans only; and that it relates to pharmacology only. But even a plain reading of Section 3(d) clarifies that not only this Section applies to non-human targeted drugs (viz. veterinary drugs), but it also applies to other chemicals (that may have nothing to do with pharmacology, e.g. agro-chemicals or fertilizers, etc.), many of which cannot even be tested on humans due to which their 'therapeutic effect on humans' cannot be known. If the Novartis interpretation is applied, then such chemicals/drugs become non-patentable.

Another problem with the 'therapeutic efficacy' interpretation is that it assumes the presence of a prior art for comparison of efficacy/enhanced efficacy. The prior art may not be present in all cases and, hence, efficacy comparison under Section 3(d) can neither be actually performed even if the Novartis interpretation is followed, nor be actually applied in such cases of new inventions without prior art because the presence of a prior art is a *sine qua non* for Section 3(d)'s applicability.

Yet another problem with Section 3(d) is that the Explanation ('… significant differences in properties with regard to efficacy …') expands the scope of the main section ('… enhancement of known efficacy …'), which is contradictory to a general jurisprudence that an 'explanation' cannot expand the scope of the main Section.[27]

United States of America: FDA[28] mostly uses the term 'effectiveness', instead of 'efficacy'. It defines 'efficacy' as 'the findings in an adequate and well-controlled clinical trial or the intent of conducting such a trial and the term 'effectiveness' refers to the regulatory determination that is made on the basis of clinical efficacy and other data.'

European Union: The European Commission also does not define 'efficacy' concretely. EC's European Medicines Agency (EMA)[29], definition is not concrete because the 'efficacy' concept is treated jointly with 'safety' and talks mainly in terms of 'significant

clinical benefits' that vary from disease to disease.[30] Major portions of the Indian Section 3(d) seem to have been imported from Article 10(2)(b) of Directive 2004/27/EC[31], a regulatory directive, defining a 'general medicinal product' as follows:

> 'a medicinal product ………. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorized active substance must be supplied by the applicant.'

Since marketing and patenting objectives are different, it is questionable whether Section 3(d) should be defined in terms of the drug regulatory law or the patents law.

'Efficacy' in Practice in India

All patent regimes have left the 'efficacy' concept undefined. Although the current author advocates for its wider interpretation, yet there is a big debate in India, hovering around its narrow *vs* wide interpretation. In his recent stand, Basheer submitted in his intervention application in the Novartis case[32], in favour of the narrow interpretation. Even in his interview in Frontline[33], he categorically argues for a narrow interpretation on account of his interpretation of the expression 'properties with regard to efficacy' in the 'explanation'. Although he admits that the '… above clause refers to only those 'properties' that have some bearing on 'efficacy' and not all properties', yet he denies that some properties, 'such as improved processability or flow characteristics, storage potential, etc.' may qualify to be covered under his concept of some properties that have some bearing on efficacy.

Nature of Cases on 'Efficacy' under Section 3(d)

Due to the 'political correctness' imperative, not many can oppose Section 3(d) and 'enhanced efficacy' for the prevention of evergreening and product-hopping. This explains why there are only a few court-cases challenging as *ultra vires*, the nature of Section 3(d) itself [e.g. Novartis case, Boehringer case[34], *Roche* v *Cipla*[35]], although there are plenty of court-cases involving the application of Section 3(d) [e.g. Asian Electronic[36]].

Mix-up between 'Patent-Eligibility' and 'Patentability'

Although 'efficacy' has been left undefined, India is the only country which uses the 'efficacy' test as a patent-eligibility test[4] while other patent regimes use 'efficacy' as a patentability test, not as a patent-eligibility test. This relates to another problem - Section 3(d) uses a confusing mix of both of these concepts. Section 3(d) explicitly belongs to the 'patent-eligibility' category, which is related to inherent patentability. On the other hand, Section 3(d)'s 'enhanced efficacy' involves not only an external patentability test of non-obviousness/inventive step, but also another external patentability test of utility, i.e. enhanced utility over the prior art.[37] Thus, Section 3(d) is a confusing mix-up where a patent-eligibility provision involves two patentability tests (of non-obviousness and utility). Normally, the patent-eligibility examination should precede and the patentability examination should follow. But in the case of Section 3(d), the patentability examination is conducted right at the beginning and under the garb of a patent-eligibility examination.[4] This conceptual uncertainty creates externalities and results in *ex post* cost (lower patent-validity and higher litigation cost).

Efficacy vis-à-vis Inventive Step

'Efficacy' is involved in the test of inventive step, as defined under Section 2(1)(ja)[38]:

> 'inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art'.

Efficacy and Non-obviousness in USA

In the USA, the test of inventive step comprises the test of non-obviousness. The historical development in the application of non-obviousness tests has been as follows – (1) Graham's Four Factor Test[39], (2) TSM Test[40], (3) KSR Test[41] and (4) the recent trend (vide *Pfizer* v *Apotex*[42]) of reverting back to Graham's Test. The Indian Section 3(d) is different in some sense, as no motivation under the TSM Test is required in India.[4]

'Efficacy' and Problems of Uncertain Concepts

Even some expressions/words in Section 3(d) themselves promote legal uncertainty, like, for instance - derivatives, known substance, new use,

discovery *vs* invention, significant, enhancement, standard of proof, burden of proof, etc. Should structural or functional similarity be the standard for derivatives? What should be the 'known substance' for 'efficacy' comparison? 'New use of new form', which involves greater inventiveness, is not patentable under the main body of Section 3; but 'significant enhancement in properties regarding efficacy', which certainly involves less inventiveness, makes it patentable. This is anomalous. What distinguishes 'discovery' from 'invention' for patentability? How much enhancement should qualify as 'significant enhancement'? In the Novartis case, even 30 per cent bio-availability enhancement was not considered as 'significant enhancement in efficacy'. Eisenberg[43] proposed PHOSITA as a solution to this problem, while the current author proposed a more refined standard,UPOSITA[24] ('unimaginative person, ordinarily skilled in the art'). If the drug regulatory norm is applied, then the issues of timing and 'standard of proof' arise–should the patent applicant file the efficacy/safety/clinical data at the time of patent filing itself? Since patent applications are made sometime around the pre-clinical stage when no clinical data are available, the expected standard of proof under the regulatory norm approach would be unreasonable or unsuitable. USPTO's guidelines provide a fair solution to this problem by stipulating that the only data required at the patent-filing stage, are the ones that have 'a reasonable correlation between the activity and the asserted use.'[44]

Issues Indirectly related to 'Efficacy'

Patent linkage, data exclusivity and compulsory licensing are some of the non-patent regime issues that have recently got indirectly linked to efficacy. The present author holds that had the efficacy-factor's definition/scope/applicability/use been properly ascertained, then all the following controversies either would not have arisen, or could have been avoided to some extent.

Patent Linkage

The Bayer case[45] brought forth the patent linkage aspect related to the 'efficacy' debate conundrum - can the patent's clinical/'efficacy' data be used to block drug-marketing approvals, if the applicant drug allegedly infringes the patented drug? A drug-marketing regulator does not have the expertise/competence/jurisdiction, legal or technical, to decide whether a drug is infringing some patent.

Even the European Commission Pharmaceutical Sector Inquiry Report[46] eschews patent linkage as anti-competitive.

Data Exclusivity

Often, the generic companies in developing countries, use the innovator patent's efficacy/safety/clinical data (relying on the principle of equivalence) to acquire marketing authorization without any waiting period. On the other hand, the developed nations often have 5 to 10 years of data exclusivity (waiting period), before which the generics cannot rely on them for their marketing authorization.[47] Although TRIPS does not mandate data exclusivity and India does not allow pharmaceutical data exclusivity[48], yet the developed countries want India to allow pharmaceutical data exclusivity.

Compulsory Licensing

This issue came into focus with the first ever (and the sole) grant of compulsory licence to the generic manufacturer Natco[49] against the patentee Bayer's drug, Nexavar. Here again, there is a North-South divide. North eschews the use of compulsory licensing under non-emergency situations, despite its TRIPS-compliance. However, Chien's[50] finding that compulsory licensing does not necessarily lead to a decline in innovation-rate, significantly undermines the basis of the North's opposition.

Compensatory 'Licensing' vs Compensatory 'Liability'

Without going into the North-South posturing, the current author finds the models offered by (1) Correa[51,52] - the Compensatory Licensing Model and (2) Basheer[53] - the Compensatory Liability Model, to be very useful in deciding whether, when and under what conditions should the compulsory licence be resorted to.

Current Author's view: 'Licensing' vs 'Liability' Models

The current author only broadly agrees with the Compensatory Liability Model of Basheer[53], while generally disagreeing with the Compulsory Licensing Model of Correa.[51,52] The current author disagrees with the interpretation of term 'unfair' within the phrase 'unfair commercial use' under Basheer's model[53] which implies that the word 'unfair' allows reliance by the Government (but not by third parties) on the regulatory data ('efficacy'/'safety' data submitted by the patentee for obtaining the marketing approval) for the purpose of granting marketing

approval to subsequent 'me-too' applicants. In the current author's view, Article 39.3 of TRIPS nowhere prescribes such reliance by the government. Moreover, the government reliance on such regulatory data is tantamount to facilitating third-party unfair commercial use. The government cannot rely on such efficacy/safety data under the guise of public interest, which has already been taken care of by several other provisions under the IPA, 1970 and other regimes. If each and every provision of the Patent Act is made subservient to the over-riding public interest factor, then the whole purpose of the Patent Act (i.e. to grant limited monopoly for innovation-promotion) will get defeated. The current author holds that had the definitions, scope, applicability and use of efficacy and data exclusivity issues been clearly settled, then the controversy regarding the reliance/use/unfair commercial use of the efficacy/safety data would not have arisen *vis-à-vis* compulsory licensing.

The foregoing discussion makes it clear that the uncertainty regarding efficacy and Section 3(d) directly and indirectly impacts various legal and non-legal aspects (viz. the L&E aspect of incentives) and, hence, a reform is needed.

Towards a Model: Efficacy -Matrix, -Score, -Threshold(Cut-off)

Integrative Approach

The divergent outcomes under various approaches of L&E, legal, political, economic (public choice) and equity call for an impartial integrated approach regarding the Balancing Imperative in reforms, which this paper attempts by developing a simple model, comprising Efficacy Matrix, Efficacy Score, Efficacy Threshold (cut-off), etc.

Reform Imperative

Legal reforms are required in two realms – (1) 'law in motion' and (2) 'law in books'.

Reform in 'Law in Books'

Legal-institutional reforms are required at various levels, *vis-à-vis* the need for balancing the incentives of the following stakeholders, viz. (1) primary inventors, (2) secondary inventors, (3) generics, (4) petty/independent/tertiary inventors, (5) medical practitioners, (6) insurers, (7) government and (8) public.

Reform in Section 3(d)

The incentives of the innovators and generics can be taken care of by reform in Section 3(d), probably as proposed in Basheer.[4]

Utility Model of Petty Patents System

The incentives of the smaller/independent/petty/ tertiary inventors can be taken care of by a totally new supplementary/alternative regime, based on the petty patents system, or the utility model[54], which originated from USA, but soon spread to Japan[55], Germany[56], China, South Korea[57], Austria[56], Australia (Delnorth[58]), Malaysia (utility innovation), Indonesia (petty patent), Taiwan, etc. It protects those inventions which cannot meet the strict patentability tests of inventiveness/non-obviousness (especially 'efficacy') under the normal patent regime.[59] In India, the Department of Industrial Policy and Promotion[60] is currently considering such a proposal.

'Indian' Orphan Drug Act

The development and patenting of orphan drugs is problematic[61] because of (1) low return on investment and (2) absence of 'novelty'. Such an Act helps by incentivizing the orphan drug developer (e.g. in the form of higher/assured rewards than the normal product patents) and also by compensating for the losses on account of lack of novelty by granting the orphan drug a market exclusivity for a few years (e.g. 7 years in USA). An Indian orphan drug law is needed[62] on the lines of the American Orphan Drugs Act.

'Indian' Bayh-Dole Act

The public-private technology transfer needs balancing for which the American Bayh-Dole Act's Indian version (i.e. Protection and Utilisation of Public Funded Intellectual Property Bill, 2008 (ref. 63) is required.[64]

Reform in Drug Price Control and Marketing Approval Regimes

A reform in these areas is also very much needed, as has been highlighted by the recent indictment of the DCGI by an Indian Parliamentary Committee, which talked about how the drug regulatory office acts in collusion with the pharmaceutical industry, at the cost of the general public[65], which has the effect of perpetuating the information asymmetry problem. Sauer & Sauer[66] suggest privatization of the drug approval process, if one wants both - cheaper drugs and the incentive to innovate.

Reform in 'Law in Motion'

The reform in 'law in motion' can be done by bringing certainty in 'efficacy' testing, through the use of the current proposed Efficacy Matrix-Efficacy Threshold(Cut-off) Model (based on the wider

interpretation of 'efficacy') by the patent authorities. This is the main focus of this research paper because no major attempt has been made in this regard.

Earlier attempt at Modeling/Quantification of Efficacy

The only known relevant quantification attempt [regarding Section 3(d) efficacy criteria] is the one by Choudhry[67] who relied on *Adams Respiratory Therapeutics Inc* v *Perrigo Company*[68] and the FDA Bioequivalence Guidelines[69], to propose that a new drug should be considered to be more efficacious, only if it did not fall within the bioequivalence range of (-)20% to (+)25% *vis-à-vis* the old drug. The demerits of this model are that (1) excepting bioequivalence, it discounts other 'efficacy'-factors, (2) the bioequivalence-range criterion is applicable only for generics, and that too, (3) only for marketing approvals. These demerits provide the motivation for the current attempt at developing a more comprehensive and generalized efficacy matrix of parameters.

Efficacy Matrix – Efficacy Threshold Model

The current author's hypothesis has not yet been empirically tested, but the author holds the hypothesis to be testable. On the basis of the historical data from various patent jurisdictions, one can identify and derive the relative importance of different relevant factors of pharmaceutical 'efficacy' and, accordingly, assign some probabilistic weightage to each. Supposing that in a data set of 1000 cases, 5 relevant factors (a, b, c, d & e) of 'efficacy' were identified. Suppose that factor 'a' occurred in 100 cases. In this eventuality, the weight assigned to factor 'a' would be given by:

Weight of factor 'a' = w = 100÷1000 = 0.1

Similarly, if 'b', 'c', 'd' & 'e' occur 200, 300, 400 & 500 times, respectively, then their assigned weightages would be 0.2, 0.3, 0.4 & 0.5, respectively. These weighted 'efficacy'-factors could then be aggregated/combined according to some formula (here, for simplicity, the author uses the simple addition formula), thereby yielding an Aggregate Efficacy Score:

Aggregate Efficacy Score (AE) = Sum of weights of all identified factors of 'efficacy'

=>Aggregate Efficacy Score = AE = 0.1+0.2+0.3+0.4+0.5=1.5

Now, the Patent Office will have to make a policy decision regarding fixation of a particular cut-off score as the Efficacy Threshold (T). Suppose, the Patent Office decides the cut-off T as follows:

Efficacy Threshold (T) = 0.4

Using this pre-determined T as the benchmark (cut-off), the Patent Office can start considering each case on its merits, by identifying the relevant factors of 'efficacy' present in that particular case, aggregating them into its Efficacy Score (E), comparing this E with the pre-determined T and if E ≥ T, then the patent application may be deemed to have passed the 'efficacy' test under Section 3(d).

If in a particular patent application (X), only 'a' and 'e' factors are present, then:

X's Efficacy Score = E = 0.1 + 0.5 = 0.6
But the pre-determined Efficacy Threshold = T = 0.4

Now, comparing E with T, we get

E = 0.6 ≥ T = 0.4
⇨   E ≥ T
⇨   Patent application X passes the 'efficacy' test under Section 3(d)

In this entire scheme, the AE and T are the benchmarks, pre-determined by the Patent Office on the basis of the historical occurrence of the various relevant factors of 'efficacy' in all pharmaceutical patent cases over time, viz., over the last 10, 20, or 50 years. *Ceteris paribus*, if a patent application meets this 'efficacy' benchmark test as well as all the other patentability criteria (i.e. novelty and utility), then the patent authority may be expected to be positively inclined towards granting the patent.

Mathematical Representation

Suppose that the Patent Office decides 'T' as the Efficacy Threshold for passing the efficacy test.

Also suppose that there are $x_1, x_2, x_3, \ldots x_n$ number of relevant 'efficacy'-factors that have been identified by the Patent Office for the purposes of 'efficacy' determination, denoted by the following:

Efficacy Matrix = $X = \sum x_i = \{x_1, x_2, x_3, \ldots x_n\}$

Where 'x' comprises all the relevant 'efficacy'-factors;

And '$x_1 = x_2 = x_3 = \ldots = x_n$' [since each of these variables x_1, x_2, x_3, etc. represents the presence of one relevant factor of 'efficacy' and can take the value of only '1'; a particular factor can be either present {= value 1} or absent {= value 0}, but the proposed model is based on only the 'presence' of relevant factor of 'efficacy' in any particular case;

And 'n' is the total number of variables;

And '$w(x_1)$, $w(x_2)$, $w(x_3)$, ..., $w(x_n)$' are the weights corresponding to each factor.

Then, the hypothesized Efficacy Score

'E' = $\sum_{i=1}^{n} \{(x_i) * w(x_i)\}$

This hypothesized Efficacy Score 'E' can be used by the Patent Office in many ways, e.g. in the following two instances, *inter alia*:

Case 1: When the Patent Office decides to assign equal weightage to all relevant factors:

i.e. $w(x_1) = w(x_2) = w(x_3) = \ldots = w(x_{n-1}) = w(x_n) = 1$

Then, Efficacy Score

$= E = \sum_{i=1}^{n} \{(x_i) * w(x_i)\} = n\{1 * 1\} = n$

Where 'n' is the total number of relevant factors present.

Comparing Efficacy Score 'E' with the pre-determined Efficacy Threshold 'T', we get

If $E = n \geq T$, = > the efficacy test has been passed &

If $E = n \leq T$, = > the efficacy test has been failed.

Case 2: When the Patent Office decides to assign differential weightage to each factor:

i.e. $w(x_1) \neq w(x_2) \neq w(x_3) \neq \ldots \neq w(x_{n-1}) \neq w(x_n)$

Then, Efficacy Score

$= E = \sum_{i=1}^{n} \{(x_i) * w(x_i)\} = \sum (1) * (w(x_i)) = n * \sum w(x_i)$

which is the aggregate weight multiplied by the total number of factors present.

Comparing the Efficacy Score E with the pre-determined Efficacy Threshold T, we get,

If $E = n * \sum w(x_i) \geq T$, = > the efficacy test has been passed &

If $E = n * \sum w(x_i)) \leq T$, = > the efficacy test has been failed.

Efficacy Matrix

The current author has previously identified[24] the following non-exhaustive list of relevant 'efficacy'-factors in the efficacy matrix:

- Bio-availability
- Heat stability
- Humidity Resistance
- Druggable-ness
- Side effects
- Toxicity
- New Drug delivery Systems/Mechanisms (NDDS)

- Dosage:
  - Quantity
  - Frequency
- Form (Tablet, Intravenous, etc.)
- Drug individualization
- Manufacturing Efficiency

Role of Patent Office in the Model

Also, before applying the model, the Patent Office will have to make the following policy pre-determinations:

(1) Identify the 'efficacy matrix' (i.e. factors relevant to 'efficacy' determination);
(2) Decide whether and how to assign either differential or equal weightage to each;
(3) Decide whether to apply simple addition or other complex aggregation formula;
(4) Decide the 'Aggregate Efficacy Score' (AE) and Efficacy Threshold / Cut-off (T);

Some Relevant Aspects of the Model

Once these background policy pre-determinations have been done, the Patent Office can take the relevant factors of each case into account, calculate the efficacy score, compare it with the efficacy threshold and arrive at a tentative decision. If the efficacy score achieved under any of these formulae is greater than the pre-determined efficacy threshold, then in the absence of other adverse factors, the patent application may be deemed to have passed the 'efficacy' test under Section 3(d).

Tentativeness of the identified relevant factors of efficacy: However, it is not the current author's argument that the Patent Office should accept all the aforementioned relevant 'efficacy'-factors as conclusive because the factors identified herein are

not exhaustive and are merely suggestive. Also, proper weightages, after an empirical analysis, have yet to be assigned to these factors.

Scalability: The current model is scalable enough to accommodate an infinite number of additional relevant 'efficacy'-factors. So in future, the Patent Office may determine which additional factors are relevant and add them to the existing efficacy matrix.

Flexibility: The current model is also flexible enough to substitute the suggested aggregation method based on simple addition, with a weighted probabilistic addition, or with any other complex method/formula if it can develop any such method/formula on its own.

Rule of thumb: The proposed model is not meant to be applied as a 'rule'. Instead, it may be applied as a guideline/rule of thumb in cases where there are no extra adverse circumstances. This rule of thumb model may be published as a guideline in the official publication 'Manual of Patent Office Practice and Procedure'[70], which although not binding as a law, yet serves as the official guideline / rule of thumb.

This scheme could be particularly efficient in the case of incremental innovations, where 'enhanced efficacy' is the issue. It will bring certainty in the application of 'efficacy' test therein. Otherwise, as is the current state of affairs, there is arbitrariness in the application of this test because of lack of any standard/guideline/rule of thumb. The lack of 'efficacy' standard and the resultant vast discretion in the hands of the adjudicators, provide a fertile ground for arbitrariness, inconsistency and even malpractice/corruption. The same patent application may have different outcomes (on 'efficacy' issue) before different patent controllers, or even before different Patent Offices. This uncertainty/inconsistency encourages forum-shopping by patent applicants. The proposed model will help in checking these negative aspects.

Conclusion
At the Model Level
The current author has attempted to redress the aforementioned problems through the proposal inherent in the current hypothesis. The adoption of author's proposed 'Efficacy -Matrix, -Score, -Threshold (Cut-off)' scheme (based on the wider interpretation of 'efficacy') ' as a guideline/rule of thumb for 'efficacy'-determination under Section 3(d)

shall reduce the arbitrariness, inconsistency, corruption, etc. to a good extent, even if other legal-institutional reforms (as outlined in this paper) are not carried out. The resultant legal certainty will not only have *ex post* litigation cost reduction effect, but also have the *ex ante* rationalization effect through positive signaling. Also, it will have incentive rationalization and innovation-promotion effects. These effects will lead to Pareto-superior welfare-enhancement in the patent regime.

At the Analytical Approaches Level
Drawing upon the current author's discussion on the issue of 'efficacy' from the law and economics perspective[71], a strict adherence to any one of the approaches (i.e. political economy (geo-political), economics, law and economics, equity and legal) might lead to differing or partial analyses and solutions, just like classic story of the five blind men and the elephant, where each blind man describes the elephant on the basis of his limited experience of the elephant's body-part that he touches. The political economy approach calls for the increased long term incentives for the geo-political factors, so as to reduce the extent of geo-political interference. The pure/rationalist economics approach is concerned only with pure maximization of benefits, regardless of the identity of the beneficiary. The L&E approach talks in terms of efficiency and welfare maximization. The behavioral L&E approach adds the angle of socially-mediated role of law (i.e. norms) in any Pareto-superior step. The equity perspective calls for a level-playing-field. The legal perspective calls for a reform in 'law in books' as well as 'law in motion'. The current author adopts an integrative approach towards the balancing imperative, i.e. the need for balancing amongst the different incentives, at various levels, e.g. balancing amongst the various stakeholders, between North and South, amongst innovators, generics and petty producers, between producers and public, between primary innovators and secondary innovators, at the international level, at globalization harmonization level, etc. Since a comprehensive systemic reform in 'law in books' is not forthcoming, a very good way to meet this integrated balanced reform imperative is to reform the 'law in motion'. The proposed 'Efficacy Matrix – Efficacy Threshold' model is a concrete step in this direction itself. It will bring legal certainty, thereby save a lot of *ex post* transaction-, information-, litigation- and other costs. It will realign the current skewed incentive structure,

reduce externalities and also reduce the need for any geo-political interference. If it utilizes the concepts of the 'nudging' and 'expressive function of law' prudently, it will cure the problems of negative signaling and 'resistance to change'. The overall effect will be Pareto-superior and welfare-enhancing. Not only all the drug-manufacturers will benefit from inventive-rationalization, but most importantly, the general public will benefit from relatively cheaper and easier access to drugs, through the increased innovation-rate for new molecular entities (NMEs) in the long run.

Policy Implications

As the current author has put forward earlier[71], the proposals have policy implications at the domestic as well as international levels. They call for domestic as well as international harmonization of IPR regimes and increased public-private partnership in pharmaceutical research.

Future Research

Since the current paper is merely a theoretical one, it has to be empirically tested. Since the proposed model is scalable/flexible/refinable enough, it can be considered, after necessary modification, for application to even non-pharmaceutical patents examination. Future research may also focus on the nature of reforms, i.e. whether the choice architecture should be designed on the gentle 'nudge' approach or full state interventionist approach. Despite the current author's advocacy for the gentle 'nudge' approach, yet counterfactual researches on the line of 'full state intervention', are also required for a proper comparison of the entire dynamics. Public-private partnership in pharmaceuticals is another area of future research. Gene patenting is an emerging problematic research area which the patent regime will have to address, sooner or later. The possibility of transformation of the Indian generics industry into primarily innovating industry holds another promising area of research. The current author holds that a mere 'nudge' by the political leadership/legislature will embolden the corporate culture/leadership to take the quantum 'leap of faith' from generics to innovation. But, this is not to argue that India should leave its generics core competence. Instead, the argument is to diversify and put primary focus on innovation, but retain the generics strength. There are many examples of innovative companies acquiring generic companies[72,73] (or vice versa[74]). There is no reason why India, too, cannot pursue both strategies simultaneously.

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