

Section 3(d): 'New' Indian Perspective

Aditya Kant[†]

New Delhi Chambers of Law, 1st Floor, 6, Babar Lane, Bengali Market, New Delhi 110 001

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Instead of the theoretical approach, this article attempts to visit the famed Section 3(d) of the Indian Patents Act from a practical viewpoint. Examining the relevance and actual working of this Section in the Indian context, this article not only emphasizes the need to retain it, albeit in a modified form, but it also attempts to strike a balance between the competing, and seemingly conflicting interests of various 'interest groups' and their ideologies of various shades at different levels, viz. *national v internationalism, under-developed/undeveloped/developing nations v developed nations, generics v innovators, Indian companies v MNCs, public interest v commercial interest, socialistic policies of a welfare state v capitalism*, etc. While still advocating for its (modified) existence, this article does not restrict its advocacy to narrow traditional jingoism; rather, it urges the Indian stakeholders, especially the Indian companies and the Indian Government to use this nobly-intended provision as an 'opportunity' to transform itself from the 'inventing around' players to the 'inventing' players, thereby enabling the nation as a whole to catapult itself into the big world pharmaceutical league. For the protection of incremental innovations, the author advocates enactment of a supplementary 'petty' patent system.

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Relevance of Section 3(d)

This author would rather begin with the hitherto less-known and now passé Gramscian¹ concept of 'War of Positions' (quite distinct from the related sister-concept of 'War of Manoeuvre'), albeit with a different and wider interpretation in an altogether different context. Patent regimes are territorial, i.e. they are country-specific. The TRIPS² and the subsequent Doha Declarations recognize not only this, but they also provide sufficient 'discretion/flexibility' [Article 27(2) and 27(3)] to national governments to mould (under certain conditions) and implement the international treaty obligations according to their peculiar needs and circumstances. Thus, various patent or national jurisdictions adopt different postures and viewpoints on several issues, on which flexibility has been granted. These adaptations are actually 'policy levers'³, with which developing and under-developed nations try to mitigate some of the disadvantages associated with the 'free-for-all' patent regime advocated by the developed nations. For example, India, being a developing nation, has different approach to the notion of 'incremental development/invention' than the developed nations, viz. USA, and hence, the 'War of Positions'. So far,

this politico-ideological and economic 'War of Position', has best reflected itself in the so-called '*generics v innovators*' war. Traditionally, India has taken the position aligning with the largely 'innovation-averse' generic pharmaceutical industry. The million dollars (literally) question that arises is whether India, especially if it aspires to become an economic superpower, can afford to be so myopic and innovation-averse. And if yes, then at what cost?

One of the manifestations of this so-called '*generics v innovators*' war is the famed Section 3(d) of the Indian Patent Act, 1970, vide the amendment of 2005. On one hand, its origin lies in generics-centred mind-set of the nation, as a whole; on the other hand, it has the 'seeds of innovation' inherent therein, though very few have been able to discern it, so far. Depending upon which side of this '*generics v innovators*' divide one is situated, the interpretation and use of Section 3(d), alongwith its Explanation, accordingly varies. At the international level, this is influenced by the 'developed/developing/under-developed' status; at the national level, it is largely influenced by the politico-ideological mood of the nation, collectively reflected in the stand taken by the leadership; at the corporate level, it is primarily influenced by the sheer economics, as none of the corporate entities (especially in India) have ever

[†]Email: adityakant@adityakant.com

actually shown a pure altruistic or humanitarian approach towards patenting; at the individual level, it is driven by the need for cheap and easy availability of drugs to the masses, which unfortunately has largely been a chimaera. The stand taken by any particular entity or a group can be reasonably predicted, if one keeps the foregoing factors in mind. Everyone is waging a war from (and for) its own position and this is true not only in the pharmaceutical patenting, but also in all walks of life, at all levels.

In India, Section 3(d) is largely an attempt, albeit half-cooked,⁴ to prevent the pharmaceutical giants from indulging in 'ever-greening'.⁵ In order to be TRIPS-compliant, but at the same time, also to safeguard the genuine concerns and aspirations of a developing nation, India allowed product-patenting for drugs, chemicals and food (agro products), vide the amendment of Indian Patents Act in 2005. The product patent regime brought about an upsurge in patent filings and, in many cases, consequent litigations also. The Indian generic pharmaceutical industry, known for its prowess in reverse engineering, started feeling the heat. However, Section 3(d) came to their rescue, albeit myopically, to those who believed in 'patent busting', thereby resulting in large numbers of pre-grant and post-grant oppositions under Section 25(1) and 25(2), respectively. In this bandwagon, the patients' associations and NGOs also hopped on. Apart from the pre- and post-grant oppositions, some of the generic pharmaceutical companies started adopting a rather aggressive approach, whereby they started challenging the very validity of some patents by directly infringing them.⁶

This 'challenge by infringement' approach is being adopted in those cases of patents, where there are some perceptible lacunae (e.g. technical, procedural, or even inherent weaknesses on 'patentability' or 'patent eligibility' criteria) in the patents that have already been granted. This aggression was facilitated by the crude combine of jingoistic (often narrow) and socialist sentiments, which took oblique recourse to Section 3(d) to secure its vested short-term interests. The real legislative intent behind Section 3(d) was to prevent 'ever-greening', which was a noble and genuine national interest.⁷ But some unscrupulous pharmaceutical companies turned a noble provision into some sort of a weapon to stall even genuine patents. This vested expansion of the real scope of the said Section 3(d) was intentional (for obvious

commercial reasons) on the part of generic companies and nationalistic on the part of the judicature and legislature (sometimes driven unconsciously or sub-consciously by the socialist ideological hangover). But in this conundrum, the essence, spirit or rationale of the patent regime itself was given a short shrift.

The patent regime strives to strike a balance between the monopolistic interests of a patentee on one hand and the collective or public interest, on the other. This delicate equilibrium has been disturbed by the expansive, and often mis-applied,⁸ interpretation of Section 3(d). The expansive interpretation and frequent mis-application of this (originally noble) provision ostensibly seeks to protect the domestic generics industry in the short term, but the proponents of this sectional over-reach (i.e. the myopic generic companies) fail to realize that the same provision works at cross-purposes with its implicit intention of protecting the generic industry. This is so because this Section and its Explanation proscribe patenting of incremental improvements (e.g. selection inventions, product-by-process inventions, 'new use' inventions, etc.), which has traditionally been the forte of Indian pharmaceutical companies.

So, far, the Indian pharmaceutical companies have not excelled in the field of real 'new molecular entity' or 'new chemical entity' (NME/NCE) innovation. By and large, peripheral aspects and 'inventing around', viz. small incremental improvements over the existing drugs, or their delivery-mechanisms, processes of manufacturing, etc., rather than the 'new invention', have been their mainstay. No doubt, under the typical Indian circumstances of poverty, limited resources in terms of infrastructure, etc., the incremental and peripheral inventions assume great significance and their 'patentability' or 'patent eligibility' should be a matter of great concern for the policy-makers. For example, a particular patented drug delivery system (US Pat No 6,623,762 granted in 2004 for a vaccine) can tolerate heat up to 55°C for quite a few months under conditions that would have normally destroyed the vaccine in any other drug delivery system.⁴ Thus, 'by eliminating the need for refrigeration, the technology could save up to \$300 million a year in global vaccine costs, which means another ten million children, could be protected. Currently 50% of all vaccines may be wasted in part due to temperature damage.'⁹ Similar is the case of 'Aluvia', which however is an application from the other side of the 'generic v innovator' divide. Shamnad Basheer

reports that from the Pre-Grant Opposition filed by I-MAK against Abbot's application claiming Aluvia, which is a 'heat stable' combination form of an anti-retroviral drug, consisting of Lopinavir and Ritonavir, it appears that the resultant is an increased water-solubility, better bioavailability, more stability, lower pill-burden and, hence, the storability without refrigeration.¹⁰ In his paper, Sudip Chaudhuri observes that the development of new drug delivery systems (NDDS) products has now become one of the major thrusts area for most of the Indian pharma biggies.¹¹

However, despite the afore-mentioned need for greater sensitivity on the part of patent policy-makers, what the Indian legislature has given to the generics industry by the right hand, the pseudo nationalist-socialist-commercial combine is attempting to take the same privilege away by enforcing the expansive interpretation of the originally nobly-intended provision. The resultant of this myopic influence is the insular protectionism, which is going to harm both, intrinsically as well as extrinsically the same industry in the long-term. It would harm intrinsically, because the generic industry would soon realize that its expansive interpretation would disallow incremental improvements, which is their mainstay. Most Indian pharma biggies survive largely on supply of generic drugs to the outside world. They specialize in non-therapeutic inventions, or more precisely 'inventing around inventions'. For example, Ranbaxy's CIPRO pill, a novel drug delivery mechanism, sold as Cipro-OD, enables a patient to take the medicine just once a day (OD). However, under the Explanation to Section 3(d) of India's Patent Act, Ranbaxy's drug will qualify as a 'combination' only and, therefore, non-patentable, unless it somehow is able to prove 'significantly enhanced efficacy' over and above Bayer's CIPRO.¹² It would harm extrinsically because ensconced in the State-protectionism, the domestic generic industry would never get motivated enough to aggressively engage or re-focus itself on the process of core or innovative new drug (NME/NCE) inventions. Protectionism engenders, at the least, a sense of complacency, if nothing more. Naturally, the rate of innovation is bound to decline gradually, or stagnate. And along with it, will decline our national clout in the comity of nations because unless a nation becomes strong in its own right, it cannot bargain advantageously in the international arena. Hence,

until Indian drug companies re-focus their vision towards developing new innovative drugs (NME/NCE), they will remain marginal players in the world pharmaceutical scene. Generics, at their best, are peripheral players because they owe their *raison d'être* to Innovators. This proposition can be tested with the help of the data on 'mailbox applications'.¹³ On analysing the data the following inferences may be drawn:

- (i) Indian 'mailbox applications' formed only 14.8% of the total 9080 applications;
- (ii) It appears that overwhelming number of the patent filings (whether by Indians or MNCs) were for the 'derivatives of the known substances or uses, etc.' [in the sense of Section 3(d)] and only a few were for the NME/NCE;
- (iii) The data is exemplary of the factum of low share of Indians.

Thus, it is evident that the Indian pharmaceutical companies lag in patent development and filing. This lag is even more pronounced in 'product' patent filings, as distinguished from other forms of patents, viz. process, etc. The 'truly Indian' product patent filing picture becomes even more dismal, if we discount the following from the total number of Indian product patent filings:

- (a) Product patents filed by Indian arms of MNCs;
- (b) Product patents filed by resident Indians, as part of an MNC; and
- (c) Product patents filed by Indians abroad (i.e. NRIs and PIOs).

Thus, truly Indian (such patents whose primary benefits accrue to Indians, and not to MNCs) product patenting for NME/NCE is minimal. Although at present, this is just an untested hypothesis, yet if it is true, then the author has no hesitation in observing that the generic pharmaceutical industry is unscrupulously (and under mistaken belief) using the Section 3(d), largely for the purpose of 'patent busting' of the already granted patents of MNCs. The Indian generic pharmaceutical industry is still in a lethargic mode, nurtured so meticulously by the State during the protectionist era, little realizing that the days of protectionism (in patenting, as well as most other fields) are practically over and if it would not shun 'mediocracy' for the 'meritocracy', it will no longer strive to be counted amongst the big players of even the world generic pharmaceutical industry, what to talk of the world's pharmaceutical field in totality. Competition from the so-called 'third world' and

'developing' countries and China is not going to make its existence any cosier. Moreover, many other (competitor) countries are contemplating of enacting protectionist provisions similar to the Indian Section 3(d).¹⁴ What would happen to Indian slumber-happy generic sloths, if this 'collective action problem'¹⁵ arises? So, 'caveat generics', either girdle up, or get marginalised at the world scene.

In this regard, the recent developments¹⁶ are worth taking serious note of. For example, several 'in-transit' EU seizures of Indian generic product consignments across Europe; high percentage of generic pharmaceuticals seizures by the US customs; US FDA's recent de-recognition of a major Indian generic exporter's manufacturing facilities; and some African countries, viz. Uganda, Peru and Ghana and Kenya are now enacting a new 'anti-counterfeit' legislation under the pressure of European MNCs, which signifies a trend towards maximalist IPR enforcement attitude. In fact, Kenya has already passed the Anti-Counterfeit Act in December 2008, whereby it recognises intellectual property rights of pharmaceutical products registered in any part of the world and not just in the country of export or import, which means intellectual property rights of a pharmaceutical product patented in any other country, can be enforced, e.g. in a sale of the generic version of the drug by India to Kenya.

However, there are some positive signs, also. If not the Indian generic companies, then at least the Indian Government certainly seems to be cognizant of the gravity and implications of these developments, especially the one in Kenya, as is evident from the Indian Commerce Secretary, Mr. G K Pillai's call for an extraordinary meeting of Ambassadors of all African countries on 24th April 2009, regarding the new development. On the flip side, however, if even these alarming signs are unable to jolt the Indian generic companies out of their splendid slumber (under the protectionism), then they should abandon their international dream of becoming big players on the world pharmaceutical scene. In that case, they will always remain merely Indian players. So, generics, rise to the occasion, or perish from the international arena! Strive to be innovators; the generic spin-offs, offshoots and by-products will automatically follow in the wake of the innovations. It is precisely in this context that the constructive use of Section 3(d), instead of the retrogressive use thereof in 'patent busting' of the already granted patents is proposed.

'Invent' yourself; don't merely 'invent around inventions'. Of course, where there are wrongly granted patents, the Section 3(d) must be used to bust them. But such 'patent busting' should not become the major growth vehicle or focus area for the Indian generic companies; instead, they should re-focus themselves on the R&D for 'new inventions', not merely 'inventing around inventions', as the latter is discouraged by the Section 3(d) in any case.

Section 3(d): Legal Aspects

As per the extant Indian Patents Act, an inquiry into the grant of a patent actually starts with an examination of the eligibility for patenting, but subject to its patentability *vis-à-vis* (i) novelty, (ii) inventive step (containing non-obviousness, too) and (iii) industrial application. Though some scholars may argue that patentability examination should have been undertaken first, despite the fact that there are certain infirmities in the current scheme and formulation of the relevant Sections, it is largely correct to undertake the 'patent eligibility' examination first, as it owes its existence to certain flexibilities accorded to certain countries under Article 27(2) & (3) of TRIPS. Actually, the real problem with this Section lies elsewhere, i.e. in the poor drafting (may be, due to imperfect understanding of these underlying concepts) of the Explanation to Section 3(d), which, despite being a test of 'patent eligibility', indirectly incorporates a test of patentability (in the form of test of efficacy, wherein tests of inventive step, non-obviousness, utility can be implicit), too. Ideally, the Section should have been formulated in such a way as to keep the 'patent eligibility' test quite distinct from 'patentability' criteria. Section 3 of the said Act enumerates inventions that are not patentable under the Act. Section 3(d) denies patent eligibility to new forms of known molecules, unless they contribute to higher efficacy over the prior form. The Explanation to Section 3(d) sets the bar of patent eligibility even higher, as it considers the derivatives of known substances to be the same substance, unless they differ significantly in properties with regard to efficacy. This part of the 'Explanation' to Section 3(d) reveals a test of patentability with 'enhanced efficacy' as the criterion. Thus, an efficacious derivative form, *vis-à-vis* the known form, becomes the subject-matter of consideration for the grant of a patent.¹⁷

This Section inheres, *inter alia*, one of the tests of patentability, namely, the test for inventive step,

which entails the tests of non-obviousness and utility, too. Thus, it is clear that what is ostensibly a test of patent eligibility is actually nothing but largely a test of patentability. Hence, although it can be argued that Section 3(d) is a 'reiteration of the obvious', or that it is superfluous, or that it is inherent in the patentability tests itself and, therefore, need not have been there in the Act, yet such an inference seems to be only partly correct and this view finds echo in the observation of the Hon'ble High Court of Delhi at the preliminary injunction stage in the most recent ongoing product-patent infringement battle, namely, *Roche v CIPLA*. It may certainly seem to be a little ironical that the test of 'patent eligibility' actually boils down to tests of 'patentability'. The former is very similar to the test of non-obviousness or inventive step, i.e. 'technical advancement' as compared to the existing knowledge. The significant difference in properties with regard to efficacy shall always be with regard to the technical advancement over the existing knowledge. The territorial nature of IPR and the flexibility provided under TRIPS, when exercised by a nation depending on its socio-economic condition, determine what constitutes a patentable subject-matter within that jurisdiction. The Indian Patents Act, vide its Section 3(d), attempts to do exactly that. The said Section discourages incremental inventions from being 'patent eligible', as they are deemed to be mere discoveries of a new form of a known substance and which do not result in the enhancement of the known efficacy of that substance. The Explanation attached to the said Section further qualifies the 'enhancement of the known efficacy', by stipulating that the derivatives of the known substance shall be considered to be same substance, unless they differ significantly in properties relating to efficacy. Inventive step is defined as feature of an invention that involves technical advance as compared to the existing knowledge which makes the invention non-obvious to the notional skilled person.

Kamakhya Srivastava opines that the 'enhanced efficacy' requirement under Section 3(d) and the inventive step definition may be apparently co-terminus, as both involve technical advancement over and above the existing prior art. In the pre-grant opposition of Nevirapine (pediatric suspension of Nevirapine Hemihydrate), the Asst. Controller denied the patent, by finding lack of inventive step in the absence of any disclosure of the advantage of smaller particle size (1-150 μ) in the composition. By applying

the test of patent eligibility, the denial was specifically on the ground of failure in placing the data relating to therapeutic effect of the known substance and the claimed substance (derivative), on record. Both investigations, i.e. determining patentable subject-matter and inventive step, harp on the advancement in the form of enhanced efficacy in the former, and on the cause leading to it in the latter.¹⁷

The above scenario reflects a peculiar position in substantive patent law, where the concept of the test involved in a subsequent stage of enquiry, i.e. test of inventive step or non-obviousness, is ingrained in an earlier enquiry of patentable subject-matter, thereby making the two stages overlap. In this 'vicious cycle', the dynamics of interplay between these two stages are not clearly demarcated and elements of the inventive step (patentability) enquiry can be discerned in the Explanation to Section 3(d) (patent eligibility enquiry). The part elucidating enhancement of the known efficacy in Section 3(d) was supposedly put in to ward off 'ever-greening' of an existing patent, thereby taking care of the national interest. This intent may be laudable, but the poor formulation thereof, coupled with imperfect understanding of underlying principles related to patenting, has lend credence to a pertinent issue-whether a 'test' built-in as an inalienable part of a subsequent stage, can have its counterpart or equivalent in the preceding stage?¹⁷ Doesn't this circularity create incoherence? This is not the only incoherency in the said Section 3(d) and its Explanation. However, these incoherencies can be tested with the help of '*Novartis*' case.

Novartis Case

India opened its gate for 'product' patenting in 2005 and *Novartis (Glivec)* case has been the first high decibel case on the issue.¹⁸ However, an even bigger product-patent related case is the still ongoing *Roche v Cipla (Tarceva)* case.⁶ In these two cases, the issues and arguments were/are different in many ways. The author intends to take up only the *Novartis (Glivec)* case, as he has represented Roche/OSI in the *Roche v Cipla (Tarceva)* case and, hence, cannot observe/opine thereupon in detail. Moreover, the *Tarceva* case is still sub-judice.¹⁹

In re Novartis, the yardstick of 'efficacy', *inter alia*, and its manifestations formed the subject-matter of controversy, eventually resulting in the denial of patent for Glivec in India. Despite the fact that the determination of 'efficacy' appeared to be a little

faulty, the Madras High Court correctly upheld the constitutionality of Section 3(d), especially *vis-à-vis* the TRIPS Agreement. However, it is a different matter that in arriving at the correct conclusion about the constitutionality of Section 3(d), the Court employed a faulty constitutionality analysis.²⁰

Salient Facts of the Novartis Case

- Drug Imatinib.
- Trade name Glivec.
- For the treatment of Chronic Myelogenous Leukemia (CML).
- 1993- Novartis filed for patent over the ‘free base’ and all salt forms of Imatinib. This form was ‘non-druggable’.
- Incremental improvement resulted in Imatinib Mesylate.
- Further incremental improvement resulted in discovery of the most stable polymorphic form, i.e. beta crystalline form of Imatinib Mesylate.
- Still further incremental improvement resulted in developing the beta crystalline form of Imatinib Mesylate into a pharmaceutically useful drug, i.e. Glivec.
- 2001-US FDA approval for Glivec.
- Novartis applied for patent in India under the provisions for ‘mailbox application’ under the 1999 amendment of the Patents Act. (In pursuance of Article 70.9 of the TRIPS).
- Additionally, till the pendency of the mailbox application for patent, Novartis also applied for Exclusive Marketing Rights (EMR) under the 1999 amendment of the Patents Act.
- 2003-Novartis was granted EMR.
- Novartis sued many Indian generic drug makers, viz. Ranbaxy (at Madras High Court)²¹ and CIPLA (at Bombay High Court), for EMR violations.
- 2004-Madras High Court upheld the EMR.
- 2005-Bombay High Court refused to uphold the EMR.
- 2005-Amendment of Patents Act in 2005 made product patenting possible in India.
- 2005-Patent Office examined and rejected the product patent application of Novartis. The rejection meant, *inter alia*, that EMR of Novartis came to an end.
- Novartis filed two appeals in Madras High Court:

- (i) For the reversal of Controller’s rejection order,
- (ii) For declaring Section 3(d):
 - (a) Unconstitutional²²; and
 - (b) violative of Indian obligation under TRIPS
 - 2007- By a Govt notification, the High Court transferred first petition to the newly constituted Intellectual Property Appellate Board (IPAB), where it is still pending.
 - 2007- The second petition was over Section 3(d), which was finally held to be (i) constitutional and (ii) non-violative of India’s obligations under TRIPS, as the Court did not possess the jurisdiction to rule over the TRIPS issue.

Dissection of Section 3(d)

Section 3 contains ‘what are not inventions’ and Sub-section (d) thereof, reads as follows:

‘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 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.’

Now, let us break this Section up into the following significant meaningful constituents, each having big implications for patent eligibility and patentability, of incremental improvements, especially, in pharmaceuticals, depending on which side of the ideological divide (*generics v innovators*) one is:

- the mere discovery
- of a new form of a known substance
- 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.

All the afore-mentioned parts have their share in imparting a particular colour to any interpretation, when applied to a given set of facts and circumstances. But the greatest importance is often accorded to the word 'efficacy', especially in the context of words 'significant' and 'enhanced'. On the negative side, this Section seeks to prohibit 'ever-greening'; on the affirmative side, it allows incremental innovations which cross the threshold of significantly enhanced efficacy. However, it has left many undefined aspects also. For example, what amount of enhancement shall be deemed to be 'significant', so as to pass the muster of Section 3(d) and its Explanation? Whether the 'drug regulatory' approach, or the 'patent law' approach should be adopted in determining the standard of proof regarding efficacy at the threshold? What exactly is 'efficacy'? Whether it has to be given an expansive-cum-literal interpretation (as innovators argue), or a limited interpretation (as generics argue and which has also been endorsed by the *Novartis* judgment in the form of 'therapeutic efficacy'). The controversial judgment of the *Novartis* case has thrown up several legal issues:

Issues under 'Constitutionality Analysis'

- Whether infringement tantamounts to violation of fundamental rights (under Article 14 of the Constitution of India) of the patentee?
- Whether Indian Parliament had the legislative competence to enact Section 3(d)?²³
- Whether the absence of any guideline regarding the terms, such as, 'enhancement of known efficacy' and 'differ significantly in properties with regard to efficacy', render Section 3(d) vague and arbitrary?
- Whether such uncanalised power in the hands of a statutory authority violates the concept of equality under Article 14?

- Whether such unrestrained discretionary power in the hands of an executive authority regarding the determination of efficacy and significant enhancement therein, tantamount to delegation²⁴ of an essential legislative function?²⁵
- Whether any 'Explanation' attached to a Section, can expand the scope of the main Section?²⁶
- Whether Section 3(d) and its 'Explanation' are TRIPS-compliant?²⁷

Issues under 'Contextual Analysis'

- Whether there is any distinction between 'ever-greening' and 'incremental improvement'?
- What is the base or the 'known substance' which should form the reference point for comparison with the incrementally developed substance?
- What should be the quantum of 'bio-availability' that would make the incrementally developed substance cross the threshold of 'significantly enhanced efficacy'. In the *Novartis* case, even 30% increased bio-availability was not considered as proof of significantly enhanced efficacy.
- Should 'efficacy' be given literal/expansive interpretation (viz. in USA and EU), or limited/therapeutic²⁸ interpretation (viz. in India, after the *Novartis* judgment) only?
- If 'efficacy' under this Section is interpreted as only 'therapeutic efficacy', then how to actually apply this test of therapeutic efficacy to food, agri-products and other chemicals, on which this Section applies as per the Act?
- Within 'efficacy', how to account for the following:
 - Bio-availability²⁹
 - Heat stability
 - Humidity resistance
 - Drug-able-ness
 - Side effects
 - Toxicity
 - NDDS
 - Dosage:
 - Quantity
 - Frequency
 - Form(tablet, intravenous, etc.)
 - Manufacturing Efficiency?³⁰

- How the Indian Section 3(d) compares with the international patent standards, especially that of USA?
 - Indian Patent Act – Steps involved in the ‘patent eligibility’ and ‘patentability’ analysis:
 - Whether a ‘derivative’?
 - Whether ‘enhanced efficacy’?
 - Whether ‘patentable’ *vis-à-vis* the following criterion:
 - Novelty (anticipation – relative and absolute)
 - Inventive step (non-obviousness)
 - Utility
 - USA–Steps involved in ‘patent eligibility’ and ‘patentability’ analysis:
 - Whether ‘structural similarity’?³¹
 - Whether ‘unexpected/surprising results’?³²
 - Whether ‘motivation’ (TSM)?^{33,34}
 - New/emerging legal trend, as reflected by *Pfizer v Apotex*³⁵ case
 - Whether the distinction between ‘physical’ (secondary) and ‘biological’ (primary) properties is tenable?
- Is Section 3(d) unique³⁶ to the Indian Patent law, or has it been adopted/adapted from elsewhere?³⁷
- Should one define Section 3(d) in accordance with the ‘drug regulatory law’, or the patent law (both of which have quite different implications)?
- When even in the mature patent jurisdictions, viz. USA and EU, the term ‘efficacy’ has not been explicitly defined or definable, then was it necessary for the Judge in the *Novartis* case to define ‘efficacy’ in the very first case on product patenting in India? The US FDA 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’.³⁸ EMEA Drug Regulatory Directives, also, appears to be treating ‘efficacy’ as a variable concept.³⁹
- Is the term ‘efficacy’ definable at all, or it has to be left to the facts and circumstances of each case?⁴⁰
- Whether the *Novartis*’ Judge’s determination of ‘therapeutic efficacy’ is the ‘*ratio decidendi*’⁴¹ or the ‘*obiter dicta*’⁴², which will decide whether this determination shall be binding on the IPAB while deciding the first petition which is still pending before the said IPAB?
- Whether there was any legislative haste in passing Section 3(d) (Lok Sabha debate, 22 March 2005)?
- Whether Section 3(d) is a ‘patent eligibility’ test or ‘patentability’ test?
 - The ‘patent eligibility’ standard under Section 3(d) involves ‘enhanced efficacy’, which in turn involves non-obviousness test. Non-obviousness further involves ‘inventive step’ and ‘invention’, which is one of the tests of ‘patentability’. Thus, there is considerable intertwining and, hence, the confusion, too.
- How to interpret the term ‘derivative’?
 - Whether expansive or restricted meaning or scope?
 - ‘*Structural similarity*’ v ‘*functional similarity*’.
- What is deemed to be a ‘known substance’, against which the efficacy of the incrementally developed substance has to be compared (in *Novartis* case, should it be the Imatinib’s free base, or the mesylate form, or the beta crystalline form)?
- Anticipation aspect:
 - ‘*Relative novelty*’ (prior use or knowledge) v ‘*absolute novelty*’ (prior publication or art)
- *Discovery v invention*.
- Standard of proof (regarding efficacy data)⁴³
 - Whether to adopt:
 - Drug Regulatory approach (very onerous in pharma), or
 - Clinical test approach (reasonable in pharma field)?
- Determination of ‘significance’: case-by-case approach.

- What is the standard of person testing the patent? Standard of 'person having ordinary skill in the art' (PHOSITA) or 'unimaginative person, ordinarily skilled in the art' (UPOSITA)?⁴⁴
- What incremental developments or 'selection invention' should be 'patentable' or 'patent eligible'? For example,
 - In Europe, in 1980's the list of the drug's properties eligible for patenting was relatively limited to the following:
 - Primary uses,
 - Process and intermediates,
 - Bulk forms,
 - Simple formulations,
 - Composition of matter.
 - But during 1990s, the list grew to 18 (approx), which included the following:
 - Expansive number of uses,
 - Methods of treatments,
 - Mechanism of action,
 - Packaging,
 - Delivery profiles,
 - Dosing regimen,
 - Dosing range,
 - Dosing route,
 - Combinations,
 - Screening methods,
 - Chemistry methods,
 - Biological target,
 - Field of use, etc.

These are some of the issues that demand resolution. Indian judiciary is not yet mature enough regarding product patenting and, hence, the expectation of a flawless judgment is unreasonable at this stage. However, during the due course of time, one certainly expects impeccable judgments on product patenting, just as is the case in the rest of the fields. We must keep in mind that even mature patent jurisdictions, e.g. EU and USA, have taken centuries to reach the present stage and even they are prone to inconsistencies, even now.

Conclusion

Originally intended as a noble provision, the imperfect understanding of the contents and underlying principles of Section 3(d) by the jurists and the unscrupulous exploitation thereof by the corporates (generics), has turned this noble Section on its head. On the positive side, the restrained use

thereof has certainly resulted in checking the phenomenon of ever-greening. However, the noble provision could be made more equitable if certain changes, whether clarificatory or substantial, could be made therein.⁴ All formulations are imperfect, but still, Shammad Basheer's following proposal is a reasonable attempt at 'ironing out the creases in Section 3(d), in his own words:

'3. What are not inventions: The following are not inventions within the meaning of this Act....

d) a new form of a known substance, unless it differs significantly in properties with regard to efficacy, when compared with the known 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:

For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other structurally similar forms of a known substance shall be deemed to constitute "new forms of a known substance."

For the purposes of this clause, a "known substance," against which the efficacy of a "new form" ought to be compared, shall be taken to be a substance which is not "new," in that it does not satisfy the "novelty" criterion for patentability.

For the purposes of establishing that a "new form" differs significantly in properties with regard to efficacy, an applicant must provide data comparing the efficacy of the new form with that of a "known" substance. Such data need not prove this "difference" in property as a matter of statistical certainty, nor does the applicant have to provide actual evidence of trials in humans. Instead, the applicant has to demonstrate a reasonable correlation between the efficacy claimed and the data provided in support of this. Such reasonable evidence of the correlation can be established by relying on, inter alia, statistically relevant data documenting the activity of the new form and/or known substance, documentary evidence (e.g. articles in scientific journals), data generated using in vitro assays, or from testing in an animal model, other preclinical test data or any combination thereof.

For the purposes of this clause, a determination as to whether a difference in property with regard to

“‘efficacy’ is “‘significant,” shall be assessed with reference to the views of a person skilled in the relevant art.’

The forgoing formulation is a mere indicative suggestion, but it would certainly go a long way in opening the eyes of the policy-makers, so that they can re-draft it to effectively prevent ever-greening, and at the same time also prevent its misuse by the generic companies, thereby establishing the equilibrium that was the actual legislative intent. It should also serve as an eye-opener for the Indian generic companies to focus more on ‘inventions’ of NME/NCE, rather than on peripheral or non-therapeutic ‘inventing around inventions’ in the pharmaceutical patenting field. At another level, the policy-makers as well as the generic companies should not try to find solution to their every problem in Section 3(d). The sooner everyone realizes that Section 3(d) (even as proposed by Shamnad Basheer) should, at best, be applied to instances of ‘major’ patent cases and applications (distinct from ‘petty’ patents) only. This ‘petty’ patent issue may be the subject-matter of another full-fledged enquiry and, hence, the present author states only this much that incremental improvements, etc. can be better dealt with by a supplementary petty patent system or the ‘utility model protection system’, which is also corroborated by a recent WIPO-sponsored report (2007).⁴⁵ It is worth noting that more than 130 countries⁴⁶ have already enacted laws relating to petty patent system and India is still not awake.

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- 4 Basheer Shamnad & Reddy T Prashant, The ‘efficacy’ of Indian patent law: Ironing out the creases in Section 3(d), *SCRIPT-ed*, 5 (2) (2008) 232-266.
- 5 ‘Ever-greening’ is an informal concept in the patent field which rarely gets mentioned explicitly by judges and lawyers in patent protection cases. It often refers to the myriad ways in which pharmaceutical patent owners utilize the law and related regulatory processes to extend the life span of their ‘blockbuster drugs’ patents. ‘Linkage’ pharmaceutical ever-greening in Canada and Australia, by Thomas A Faunce (College of Law and Medical School, Australian National University, Canberra, Australia) & Joel Lexchin (School of Health Policy and Management, York University, Toronto, Canada) <http://www.anzhealthpolicy.com/content/4/1/8> (29 May 2009).
- 6 *F Hoffman-La Roche Ltd & Anr v Cipla Ltd*, CS(OS) 89/2008, Delhi High Court.
- 7 In the Parliamentary debates, the Minister of Commerce and Industry stated that Section 3(d) was introduced to prevent the phenomenon of ‘ever-greening’. Another Parliamentarian, Sh. Suresh Kurup specifically cited the ongoing case of *Glivec*, to highlight the ill effects of ever-greening, Lok Sabha Debates (22 March 2005), <http://164.100.24.230/Webdata/datalshom001/dailydeb/22032005.htm>.
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- 9 WIPO Secretariat, *Follow-on Innovation and Intellectual Property* (Submission to WHO’s CIPIH) (20 May 2005), 13-14, <http://www.who.int/entity/intellectualproperty/submissions/Innovation%20&%20Intellectual%20Property%20WIPO.pdf>.
- 10 Basheer Shamnad & Reddy T Prashant, The ‘efficacy’ of Indian patent law: Ironing out the creases in Section 3(d), *SCRIPT-ed*, 5 (2) (2008) 232-266, on the basis of the pre-grant opposition filed by I-MAK against Abbot’s application claiming ‘Aluvia’, <http://www.i-mak.org/lopinavirritonavir>.
- 11 Chaudhuri S, *Is Product Patent Protection Necessary in Developing Countries for Innovation: R&D by Indian Pharmaceutical Companies After TRIPS*, Working Paper No. 614 (Indian Institute of Management, Kolkata), 2007, 15. Gehl Sampath P, *Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Market* [Maastricht, United Nations University-Institute for New Technologies (UNU-INTECH)], 2005, argues in favour of the expansion of the scope of the term ‘efficacy’, as ‘some of the most well known inventions from Indian pharmaceutical majors have been efficacious in non-therapeutic ways.
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- Section 3(d), then the advantages sought to be gained by Section 3(d) will be neutralized at the international level. Given the fact that a large part of the international revenues of Indian biggies comes from outside the US/EU, this factor assumes great importance. Ranbaxy's Annual Report, 2005 states that total sales to be US \$1,178 million, with overseas markets accounting for 75% thereof. Of the overseas markets, the sales from the emerging economies, Brazil, Russia and China (29%) were the highest, followed by the US (28%) and the EU (17%).
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 - 16 Barooah Swaraj Paul, Generics now face trouble in Africa, <http://spicyipindia.blogspot.com/2009/05/generics-now-face-trouble-in-africa.html>.
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 - 21 The High Court of Madras first granted an order of *ex-parte* injunction in favour of *Novartis* in Suit No. 5-9 of 2004.
 - 22 *Novartis AG v Union of India*, WP No. 24759 of 2006, High Court of Madras.
 - 23 *In re JK Cotton Spinning and Weaving Mills Ltd v Union of India* (AIR 1988 SC 191), 'the Legislature is quite competent to enact a deeming provision for the purpose of assuming the existence of a fact which does not really exist'. *Novartis AG & Anr v Union of India & Othrs*.
 - 24 *In re Delhi Laws case* AIR 1951 SC 332 at para 252, 'in the absence of express powers of delegation allowed by the Constitution, the Parliament has no power to delegate its essential legislative functions to others, whether State legislatures or executive authorities, except, of course, functions which really in their true nature are ministerial.
 - 25 Supreme Court in *Jyoti Pershad v Union Territory of Delhi*. It is worth noting that Indian courts are reluctant to strike down a legislative provision solely on the ground of 'excessive delegation'. A commentary on constitutional law has pegged the ratio of success at 4:41. A P Datar, Datar on Constitution of India, 2001, 883.
 - 26 *In re Aphali Pharma Ltd v State of Maharashtra* 1989 (4) SCC 378, 'an explanation, as was found in *Bihta Marketing Union v Bank of Bihar*, may only explain and may not expand or add to the scope of the original Section.
 - 27 Ohly D Christopher, 'What's 'new'? - Isn't it obvious?' *Journal of Intellectual Property Rights*, 13 (5) (2008) 498-508, examined the proposition that Section 3(d) of India's 2005 Patents Act is not in conformity with the TRIPS, as if that question had been presented to a US Court.
 - 28 *In re Boehringer Ingelheim Pharmaceuticals*, Application No. 2845/DEL/1998, <http://www.lawyerscollective.org/content/patent-nevirapine-rejected> (19 June 2008), The application was rejected on the ground of failing to show enhanced therapeutic efficacy over the known substance.
 - 29 *In re Novartis*, even the claimed 30% increase in bioavailability was considered by the Indian Patent Office to be insufficient to satisfy the criterion of significant enhancement in efficacy under Section 3(d).
 - 30 *Torrent Pharmaceuticals Limited v Astra Aktiebolag*, Application No. 1354/DEL/98, decision dated 21 May 1998, the claimed enhancement appears to be related to 'manufacturing efficiencies'.
 - 31 *Takeda v Alphapharm*, 480 F 3d 1348 (Fed Cir 2007), the Court relied on two of its earlier decisions: (i) *In re Dillon*, 919 F 2d 688, 692 (Fed Cir 1990), it was held that 'structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness'. (ii) *In re Deuel* (51 F 3d 1552, 1558 (Fed Cir 1995), it was held that 'a known compound may suggest its homologue, analogue, or isomer because such compounds 'often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties'.
 - 32 *In re Eli Lilly & Company v Premo Pharmaceutical Laboratories, Inc*, 630 F 2d 120 (1980), the Court upheld the patentability of an oral antibiotic that was superior in terms of its mode of administration (it could be taken in tablet form, when compared with its predecessor that had to be taken intravenously).
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 - 34 *In re Eisai Co v Dr Reddy's Laboratories Ltd*, (Fed Cir 2008), p. 4, the Court of Appeals for the Federal Circuit cited *Takeda Chem Indus v Alphapharm Pty Ltd*, 492 F 3d 1350, 1356 (Fed Cir 2007). In both these cases, the CAFC found no motivation to either start or modify the lead compound. Instead, the CAFC found the prior art to be 'teaching away' there from.
 - 35 *In Pfizer v Apotex*, 480 F 3d 1348 (2007), the CAFC drew a distinction between the therapeutic and other properties (physical properties, such as, process-ability) of a pharmaceutical substance and assigned the latter lesser weight while assessing

- non-obviousness. However, another scholar, J M Mueller, does not concur with this decision and notes that ‘the Federal Circuit improperly discounted the physical, as opposed to biological (therapeutic), properties of the claimed composition. Because the Federal Circuit discounted the physical properties of improved stability and tablet processing, Pfizer was unable to rebut the *prima facie* case of obviousness based on the prior art. Mueller J M, Chemicals, combinations, and ‘common sense’: How the Supreme Court’s KSR decision is changing Federal Circuit obviousness determinations in pharmaceutical and biotechnology cases, *Northern Kentucky Law Review*, 4 (2008) 35. Eisenberg R S, Pharma’s non obvious problem, *Lewis & Clark Law Review*, 2 (2008) 375, 418, wherein she opines that the erroneous qualification of ‘unexpected properties’ as ‘secondary evidence’ in US patent jurisprudence may have led the Federal Circuit to such a decision.
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- 37 The Article 10(2)(b) of ‘Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use’ (2004) OJ (L 136) 34, defines the ‘generic medicinal product’ in terms somewhat similar that in Section 3(d).
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- 40 Mueller J, The Tiger awakens: The tumultuous transformation of India’s patent system and the rise of Indian pharmaceutical innovation, *University of Pittsburgh Law Review*, 68 (2007) 491, 553, regarding the kind of ‘efficacy’ proof required by Section 3(d).
- 41 *Black’s Law Dictionary*, 8th edn, 2004, defines ‘*ratio decidendi*’ as ‘the rule of law on which a later Court thinks that a previous court founded its decision; a general rule without which a case must have been decided otherwise’.
- 42 *Obiter dictum* is ‘a judicial comment made during the course of delivering a judicial opinion, but one that is unnecessary to the decision in the case and therefore not precedential.
- 43 Standard of proof (data) regarding efficacy that is required to be proven at the time of filing of the patent application: Special considerations for asserted therapeutic or pharmacological utilities, http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2107_03.htm. These guidelines, in keeping with case law from the US CAFC, state that when a patent application asserts a ‘therapeutic use’ for an invention, one does not have to prove the existence of a correlation between a particular pharmacological/biological activity and the asserted therapeutic use as a matter of statistical certainty, nor does one has to provide actual evidence of success in treating humans where such a utility is asserted. Instead, all that is required is a reasonable correlation between the activity and the asserted use. *Nelson v Bowler*, 626 F 2d 853, 857, 206 USPQ 881, 884 (CCPA 1980). The guidelines further provide that the office should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders, even with respect to situations, where no art-recognised animal models existed for the human disease encompassed by the claims. *Ex parte Balzarini*, 21 USPQ2d 1892 (Bd Pat App & Inter 1991).
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- 47 Before arriving at the conclusion (partly in consonance with Shamnad Basheer and mostly in dissonance with D Christopher Ohly), the present author has reviewed the entire breadth of the reference materials which formed the basis of the articles, viz. Basheer Shamnad & Reddy T Prashant, The ‘efficacy’ of Indian patent law: Ironing out the creases in Section 3(d), *SCRIPT-ed*, 5 (2) (2008) 232-266 and Ohly D Christopher, ‘What’s ‘new’? - Isn’t it obvious? *Journal of Intellectual Property Rights*, 13 (5) (2008) 498-508. The present author has already reviewed the references of the former author and they find specific mention in this article. In order to test the hypothesis of the latter author, the present author has also examined the references from Ohly’s article, which although did not find any specific mention in this article, yet helped the author in arriving at the conclusion that has been derived.