RESURRECTING ROSCOE POUND IN SECTION 3(D): THE GLIVEC GOVERNANCE

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INTRODUCTION

American Sociological Jurisprudence as elucidated in Roscoe Pound's theory applies to nearly all 'new modern' law today. The reason this paper uses the term 'new modern' is to emphasize that while a piece of legislation may be new in its existence, the same may not be modern in its origin, outlook or applicability. However, such a law may be implemented to meet the long-demanded need of its time[1]. Pound used a complex method, with a confluence of political and legal concepts incorporating pragmatism and pluralism in a body of merged ideas, practice, and proposal. This paper emphasizes the conflict that emerges out of such ideas that engulf the field of practice. These conflicts, no doubt, are vital to the existence of 'new modern' laws, while being determinate in realizing the 'balancing metaphor' that keeps the conflict of interests in check.

Perhaps, a perfect example of a 'new modern' law would be the Patents Act, 1970, as amended by the various Patents Amendment Act(s).[2] The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) being a fallout of the evolution in International Trade law[3], called for an amendment in the Patents Act to bring in harmony and uniformity across varied territorial intellectual property laws.

As a consequence of this, Section 3(d) of the Patents Act, 1970 also underwent an amendment, with the substitution[4] of Section 3(d) under the 2005 Amendment Act.[5] This revised Section became the bone of contention

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1. Several socio-economic legislations such as the Domestic Violence Act (No. 43 of 2005); Indecent Representation of Women (Prohibition) Act (No. 60 of 1986), the amendment in Hindu Marriage Act (No. 25 of 1955) with respect to coparcenary system were all new in their implementation, but the ideology/rationale behind them took birth much earlier.
2. Since 1970, the Patents Act, (No. 39 of 1970) has undergone amendment thrice in 1999 (w.e.f. 1st January 1999), 2002 (w.e.f. 20th May 2003) and 2005 (w.e.f. 1st January 2005).
3. International Trade Law primarily experienced evolution through the General Agreement on Trade and Tariff (1947), GATT 1994 and the consequent formation of the World Trade Organisation.
4. Patents Act, Section 3(d) (1970).
5. Patents (Amendment) Act, 2005.

in *Novartis AG & Another v. Union of India & Others.*[6] (hereinafter referred to as the *Novartis Glivec* case). The petitioners challenged the constitutionality of the Section and *'therapeutic efficacy'* as a standard to determine the *'enhanced efficacy'* requirement. The paper at hand, examines the presence of the conflict of interests in this controversial section, while attempting to view the correctness of the balancing metaphor as propounded by the Madras High Court[7].

POUND PREVAILING IN THE INDIAN PATENT LAW

"Sociological jurisprudence theory according to Pound should ensure that the making, interpretation and applications of law take account of social facts"[8]. Propounding the task of a lawyer to be akin to engineering, Pound aimed at building a structure of society, wherein it required "the satisfaction of maximum of wants with minimum of friction and waste"[9]. Pound seemed to render a programme towards achieving the end of this jurisprudence which consisted of eight points.[10]

To fulfill his agenda of Social Engineering, Pound classified the interests protected by law, into three primary categories (and consequent sub-categories therein), namely: Individual, Public and Social interests. Individual interests are claims or demands or desires involved in and looked at from the standpoint of the individual life.[11] These include Personality, Domestic Relations and Interest of Substance. Public interests[12] on the other hand are asserted by individuals involved in or looked at from the standpoint of political life, while Social Interests[13] are looked at in terms of social life and generalized claim of a social group.'[14]

Pound's theory also renders five Jural Postulates, in his article, *A Survey of Social Interests*[15]. The Postulates as modeled by Pound may be enlisted as:

Jural Postulate I - In civilized society men must be able to assume that others will commit no intentional aggressions upon them.

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6. Novartis AG & Anr. v Union of India & Others, (2007) 4 MLJ 1153.
7. Pronounced on 6th August 2007.
8. R.W.M. Dias, Jurisprudence 430 (Aditya Books Pvt. Ltd 1994).
9. Roscoe Pound, Interpretations of Legal History 156 (Harvard University Press 1946).
10. R.W.M. Dias, Jurisprudence 430 (Aditya Books Pvt. Ltd 1994).
11. *Ibid*, at 431.
12. *Id.*
13. *Id.*
14. R.W.M. Dias, Jurisprudence 430-435 (Aditya Books Pvt. Ltd 1994).
15. Roscoe Pound, *A Survey of Social Interests*, 39 Harvard Law Review 57 (1943).

Jural Postulate II- In civilized society men must be able to assume that they may control for the beneficial purposes what they have discovered and appropriated to their own use, what they have acquired under the existing social and economic order.

Jural Postulate III- In civilized society men must be able to assume that those with whom they deal in the general intercourse of society will act in good faith.

Jural Postulate IV- In civilized society men must be able to assume that those who engage in some course of conduct will act with due care not to cast an unreasonable risk of injury upon others.

Jural Postulate V- In civilized society men must be able to assume that others, who maintain things or employ agencies, harmless in the sphere of their use but harmful in their normal action elsewhere, will restrain them or keep them within their proper bounds.[16]

Looking at the scheme and jurisprudence backing Patent law as it stands today, it is evident that the various Jural Postulates are quite satisfied by its scheme. The first postulate may be satisfied by the freedom in India to work and develop inventions, and exercise claim over them, while the second is satisfied by the fact that a patent may be acquired[17] and rights[18] accruing thereof may be asserted. The third and fourth postulate are governed by the provisions to take action in the form of opposition proceedings to the grant of a patent[19], revocation of a valid patent[20], infringement[21] and the like, while the fifth Postulate is fulfilled by provisions such as those affording the grant of compulsory licenses[22] whereby conditions such as permission from the patentee for inventions which are not being worked are expected to be satisfied by the third party (others) desirous to make use of the patent in their field of operation.

Thus, it is quite evident from the scheme of the Act that the Patent Act is indeed a piece of Social Engineering. While there are rights conferred upon patentees, there are also considerations that are made by the Patent Office in granting those rights and consequently accruing an interest in them. Alongside, the fact that third parties at various points in time acquire the

16. *Ibid.*
17. The Patents Act, Chapter III (1970).
18. The Patents Act, Section 48 (1970).
19. The Patents Act, Chapter V (1970).
20. The Patents Act, Chapter XII (1970).
21. The Patents Act, Chapter XVIII (1970).
22. The Patents Act, Chapter XVI (1970).

right to oppose the application for a patent or file a suit for infringement takes care of their individual interests which, very often, are a manifestation of an interest favouring the larger society. Provisions such as those of Compulsory Licensing evidently depict a conflict between social and individual interests. On the other hand, an invention relating to Atomic energy not being patentable subject matter[23] is a depiction of a conflict between social, and public interest (interest in preservation of peace and order and maintaining general security) and individual interests.

SECTION 3(D) AS A CONFLICT OF INTERESTS

The paper in particular analyzes the latest ruling on Section 3(d). Section 3 deals with non-patentable subject matter and dedicates this particular sub-section to the patentability of derivatives and modified versions of products, processes or apparatus.

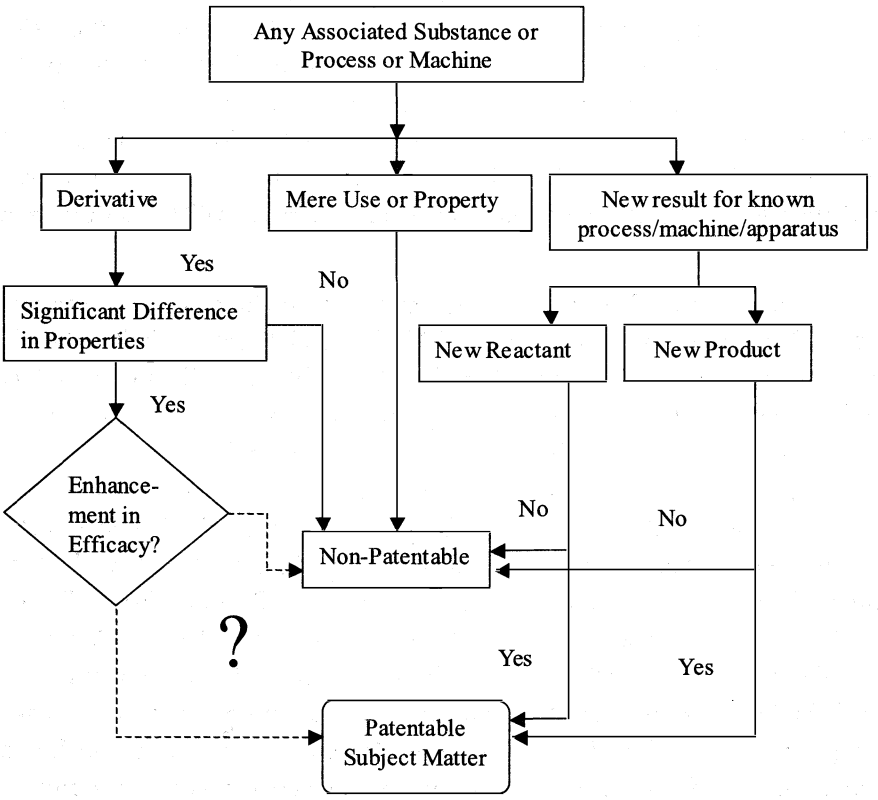
Examining the conflict of interests in Section 3(d), there exists a tug of war between individual, public and social rights. Where the question of derivative forms of chemical compounds exists, an element of similarity in properties between the derived (or modified composition) and the original composition cannot be negated. In this event, while individual interests in terms of investment in research & development, skill, labour and appending questions come under the spotlight, it is indeed necessary to determine the prevailing conflicts between other social and public interests and find the yardstick to balance the two.

Section 3(d) in terms of patentability of the derivative negates any rights to an applicant, unless and until enhanced efficacy is depicted to be existent. The public interest in doing so is the interest of the state as the guardian of social interests, which arises out of the need to conserve social interests while preserving the freedom to manufacture, trade and deal with a substance. In other words, the public interest exercised by the Patent Office, which is the State representative here, with the powers of a quasi-judicial body, protects social interests by not letting an individual rob the freedom of others in the society to use the subject-matter under contention, by granting monopoly to an individual over the same.

Inferring the intent, the section primarily seems to be aiming at preventing ever-greening amongst pharmaceutical products, assuming a high degree of physical, chemical, reactive and consequently functional similarity between various isomers and derivative forms. Further, the demand is to

23. The Patents Act, Section 4 (1970).

demonstrate to the Patent Office enhanced efficacy and hence claim one's ground to secure a patent. This factor, no doubt brings into purview the non-patentability of an incremental innovation. As a result, 'by making derivates with enhanced efficacy patentable, section 3(d) encourages the sequential development of existing products or technologies to help bring in improved products that address unmet public health needs'[24]. Inspecting a schematic flow of S. 3(d), its minutiae are revealed. For a simplistic understanding:



As represented by the schematic diagram, all the aspects appending and deciding non-patentability of the subject matter as under S. 3(d), may be arrived at in terms of an affirmative or a denial except for the aspect on enhanced efficacy for the new form of a known substance, parameters to determine which are absent in the scheme of the Act.

24. Shamnad Basheer and Prashant Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTED 232 (2008) http://www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.asp.

Roscoe Pound's greatest criticism lies in the lack of guidelines enabling the determination of the balancing metaphor to any conflict of interests. This criticism extends itself to Section 3(d) as well. The *Novartis Glivec*[25] decision pronounced by the Madras High Court, deliberating upon the constitutionality of the section, pronounced "therapeutic efficacy" as the balancing metaphor.

GLIVEC GOVERNING THE GROUND?

The *Glivec* case needs little reiteration. While the patent dispute revolved around the patentability of the beta crystalline form of *imatinib mesylate*, Novartis claimed to have obtained around 35 patents on this polymorph across various countries[26]. Owing to the unavailability of a scheme rendering patents to drugs[27], (i.e. product patents) Novartis claimed this derivative vide a "mailbox" application[28]. In the meanwhile, an Exclusive Marketing Right (EMR) had been granted in November 2003, pending grant of a product patent.

Consequently, Novartis sued generic drug makers such as Ranbaxy and CIPLA before the High Courts of Madras and Bombay challenging the grant of the EMR. The Madras High Court upheld the EMR and restrained Ranbaxy and Cipla on account of the fact that Novartis ran a free patient access programme titled "GIPAP" (Glivec International Patients Assistance Program) and undertook to make this programme even more user friendly to patients that could not afford the drug.[29] The Court held that such a step was sufficient to take care of any "public interest" ground that might have militated against the grant of an injunction. The Bombay High Court's decision is starkly opposite to that of the Madras High Court, opining that the validity of the recently issued EMR had been seriously challenged by the defendants. Besides, the fact that the drug was more expensive and was being imported by the plaintiff (triggering fears about sustained supplies of such a critical life-saving drug in India) influenced the court to deny the grant of an injunction.[30]

25. Novartis AG & Anr. v. Union of India & Others, (2007) 4 MLJ 1153.
26. *Id.* at Para 9.
27. Unamended Patents Act, Section 5 (1970).
28. Agreement on the Trade – Related Aspects of Intellectual Property Rights art. 65, 70.9, Apr. 14, 1994, 33 I.L.M 1125.
29. See Novartis AG v. Adarsh Pharma & Anr., 2004 (29) PTC 108 (Mad). See Intas Laboratories Pvt. Ltd. v. Novartis A.G. 2005 (1) CTC 27.
30. Novartis AG v. Mehar Pharma & Anr., 2005 (30) PTC 160 (Bom).

Pursuant to the 2005 amendment to the Patents Act, the scheme for product patents in the pharmaceutical sector, was introduced and the mailbox application by Novartis, as mentioned earlier, was opened and examined. The patent consequently faced opposition[31] from several generic drug companies and an NGO, the Cancer Patients Aid Association (CPAA)) on several grounds including:

i) lack of novelty/anticipation;

ii) lack of significantly enhanced "efficacy" under section 3(d);

iii) obviousness, and;

iv) wrongful priority.

In consonance with the above grounds, the Assistant Controller of Patents rejected the patent application.[32] The grant of the EMR stood lapsed with the rejection of the patent application.[33] Aggrieved by this rejection, Novartis AG, along with its Indian subsidiary, Novartis India, instituted two writ petitions in the Madras High Court, challenging the Assistant Controller's order, as also seeking a declaration that Section 3(d) was unconstitutional[34] and in violation of India's obligations under TRIPS. Pursuant to a government notification[35], the High Court transferred the first petition to the Intellectual Property Appellate Board (IPAB) and a tribunal was established thereunder to deal with appeals from the various intellectual property offices across the country. A dispute regarding the appointment of a technical member[36] also sprung up; the same having been resolved[37] by the Apex Court's interference[38], the IPAB at the time of writing this paper is hearing the appeal.

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31. Novartis AG and Anr. v. Union of India and Ors., WP No. 24759 of 2006, High Court of Judicature at Madras.
32. Novartis AG v. Natco Pharma and Others, Indian Patent Office, Application No.1602/MAS/1998.
33. The Patents Act, Section 24B (1) (1970) (as amended by the 1999 amendments). (Repealed by the 2005 Amendment Act).
34. Novartis AG and Anr v. Union of India and Ors., WP No. 24759 of 2006.
35. Notification No.12/15/2006-IPR-III, (Apr. 02, 2007), issued by the Ministry of Commerce & Industry, http://ipindia.nic.in/ipr/patent/gazetteofindia_apr2007.pdf.
36. Divya Subramanian, *Appointment Of New Technical Member To Hear Glivec Appeal*, http://www.mondaq.com/article.asp?articleid=68036.
37. Natco Pharma Ltd. v. Union of India and Ors., [Civil Appeal No.s 6004-6018 of 2008].
38. Divya Subramanian, *Appointment Of New Technical Member To Hear Glivec Appeal*, http://www.mondaq.com/article.asp?articleid=68036.

Challenging the constitutionality of Section 3(d), three issues[39] were framed. The compliance of the Section with the provisions of TRIPS was deliberated upon and affirmed. However the moot point on the validity of the amended section on the touchstone of Article 14 of the Constitution of India was deliberated and the Hon'ble Court rendered:

> *As we understand the amended section, it only declares that the very discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance, will not be treated as an invention. The position therefore is, if the discovery of a new form of a known substance must be treated as an invention, then the Patent applicant should show that the substance so discovered has a better therapeutic effect. Darland's Medical Dictionary defines the expression "efficacy" in the field of Pharmacology as "the ability of a drug to produce the desired therapeutic effect" and "efficacy" is independent of potency of the drug. Dictionary meaning of "Therapeutic", is healing of disease - having a good effect on the body." Going by the meaning for the word "efficacy" and "therapeutic" extracted above, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease / having a good effect on the body? In other words, the patent applicant is definitely aware as to what is the "therapeutic effect" of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for. Therefore it is a simple exercise of, though preceded by research, - we state - for any Patent applicant to place on record what is the therapeutic effect / efficacy of a known substance and what is the enhancement in that known efficacy. The amended section not only covers the field of pharmacology but also the other fields. As we could see from the amended section, it is made applicable to even machine, apparatus or known process with a rider that mere use of a known process is not an invention unless such a known process results in a new product or employs at least one new reactant. Therefore the amended Section is a comprehensive provision covering all fields of technology, including the field of pharmacology. In our opinion, the explanation would come in aid only to understand what is meant by the expression "resulting in the enhancement of a known efficacy"*

39. Novartis AG and Anr. v. Union of India and Ors., WP No. 24759 of 2006, Para 5.

> *in the amended section and therefore we have no doubt at all that the Explanation would operate only when discovery is made in the pharmacology field.*[40]

DOES THE GLIVEC CASE FINALLY DETERMINE THE YARDSTICK?

In the absence of a challenge before the Apex Court, the judgment appears to have finally laid the standard for determining efficacy. However, the viability of this standard as a balancing metaphor is indeed questionable for a variety of reasons.

While the patentability of pharmaceutical products are vital to safeguarding public and social interests, is it sufficient to negate the existence of an individual interest, merely because the yardstick adopted to measure the strength of the interest, moves away from a pre-determinate standard? Although amongst jural circles the lack of such a standard is perhaps the greatest criticism appended to Pound's theory, it may be visualised as the greatest strength of the patent regime. While Novelty, Utility and Non-obviousness set a standard high enough to determine the patentability of an invention, it seems that the test of enhanced efficacy is more in the nature of determining if the result of the efficacy was premeditated or not. If the same is true, then the grounds of anticipation squarely hit the patentability criterion; in the absence of it, due regard to the nature of enhancement must be given.

Several examples may be quoted to elucidate other plausible yardsticks. However, looking at the case-study at hand, it seems indeed far from equity to render such a narrow interpretation to a term, that too basing the interpretation on a meaning rendered in a medical dictionary. Pound, in his theory of Social Engineering, aimed at reducing friction between conflicting interests, which would be possible only if the impact of the interests be considered on a case-to-case basis. Pharmaceuticals and its application to biology have varied determinate parameters and effects to themselves. In this light, the use of a definite, inflexible parameter may prove detrimental to the prevailing Patent system.

Like the PHOSITA test, the balancing metaphor too should be determined on a case to case basis, depending on certain quantitative and qualitative evidence. While drug trial results, conducted at Stage III/IV could be one of the primary considerations, an absence of effect on a minor segment

40. Novartis AG and Anr. v. Union of India and Ors., WP No. 24759 of 2006, High Court of Judicature at Madras, at Para 13.

of those undergoing trials must be negated. This minority consideration, should also depend upon the spread of the disease in society, its rarity, its gravity as well as its bearing on the quality of life.

To put it differently, the view of protecting "social interests" should be looked at from a truly social standpoint. Factors such as effect on pricing, dosage, bio-availability, frequency of medication, mode of inducement and akin must be considered. In other words, efficacy should not be looked at from merely a "therapeutic" standpoint, but from one that enables improvement of the quality of life of a patient.

In my opinion, the greatest strength of Pound's theory is that the absence of a pre-determined yardstick affords to provide flexibility and helps propagate social engineering. The uniqueness of society in terms of culture, economics, genetics, anthropology and other such factors perhaps drove Pound towards rendering the concept of a yardstick. While we seem to have extrapolated his postulates and conflict of interests in an extremely sound manner to our Patent system, we seem to have ignored the flexibility needed to be inscribed into some of the provisions appended to it. The *Glivec* decision, being one of the first in the offing shall set the trend, unless an emphatic measure is taken to displace the rigidity that the decision seems to have brought, even at the stage of assessing a Patent Application.

DRAWING THE CURTAIN

The pronouncement of therapeutic efficacy as the touchstone of the validity of the provision in the ruling of the *Glivec* case must be looked beyond to accommodate other factors governing the areas, pertinently pharmacology and pharmacy. The Section undoubtedly being compliant with TRIPS is a measure to prevent "evergreening" and associated threats. However, the blind application of the judgment to all cases before the authorities may dwindle the jurisprudence behind having a progressive piece of legislation in place. The lack of a revolution imbibing factors beyond therapeutic efficacy may see the Patent system in India, crushed under the wisdom of "therapeutic efficacy", leaving almost no cure for the regime to recuperate from the social and economic damage that may accrue to drug manufacturers and patients alike.