Novelty-As Qualifier of Patentability vis-a-vis Relevancy of Section 3(D) Of Patents Act: A Critical Analysis of Indian Approach

Dr.ParthaPratim Paul[1]

I.Introduction

The definitionof "invention" in Patents Act (India)is found as: a**new product or process** involving an inventive step[2] and capable of industrial application[3]. Therefore, any invention, if it deserves to have "patent" over it, must have, as first qualifier of patentability a newness- in the form of a new product or new process.In the legal parlance, it is commonly known as NOVELTY all over the world. Accordingly, "new invention" has been defined as: **"any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the "state of the art"[4];**in another words "an invention is novel (new) if it does not form part of the existing "state of the art"; and the "state of the art" comprises all matters which are known to the public before the priority date of claimed invention by written or oral description, by use or in any other way[5].**In the legal phraseology, again "novelty" (newness) denotes that the invention regarding the subject matter of patent is not anticipated, on the basis of prior existing knowledge; Anticipation is the main narrative, put in place by the judiciary in India, United Kingdom or anywhere else, just to find the presence of "novelty" in any of the inventions. Second qualifier of patentability i.e. "inventive-step"[6]is to be determined after thatwhich is followed by "industrial**

[1]Assistant Professor, Dept. of Law, Assam University, Silchar.
[2]Patents Act, 1970, s.2(j).
[3]Patents Act, 1970, s. 2(j).
[4]Patents Act, 1970, s. 2(l).
[5]Quantel v. Spaceward, (1990) RPC 83.
[6]Patents Act, 1970, s 2(ja). "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.

application" as the third qualifier. While satisfying the three test formula i.e. sine-qua-none of patentability, Patents Act specifically excludes some inventions from patentability as INVENTIONS NOT PATENTABLE[7]; one of such is "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[8]."If it is seen that the invention falls under that above-mentioned exclusion clause, in that case, patent cannot be granted as it is not worthy to be considered for an invention or if the patent already it was granted, (if challenged) it has to be withdrawn by following a procedure.

II. Meaning of "Anticipation"

The notion of "novelty" is centred around, of "anticipation"; therefore,the term 'anticipate' needs to be explained. It means (a). to seize or take possession beforehand; (b). to use in advance; (c). to take up or deal with (a thing) or perform (an action) before another person or agent has had time to act, so as to gain an advantage; to deal with beforehand; (d). to observe or practice in advance of the due date; to cause to happen earlier; (e). to occur earlier[9]. It indicates (a). to take into consideration or mention before the due time; (b). to observe or practice in advance of the due time; to cause (a future event) to be a reality beforehand, (c). to introduce in advance of a part of a chord which is about to follow; (d). to contemplate to consider in advance[10]. In another words, "anticipate" implies (a). to imagine and expect that something will happen, sometimes taking action in preparation for it happening[11]. Similarly, it denotes (a). to make happen earlier; (b). to foresee and perform in advance; (c). to be ahead of in doing or achieving; (d). to precipitate; (e). to use or enjoy in advance[12]. **It is**

[7]Patents Act, 1970, s 3.
[8]Patents Act, 1970, s.3(d).
[9]The Oxford English Dictionary, Volume-1, 2nd Edition, 1991, (prepared by J.A.Simpson), Clarendon Press, Oxford, Page-522.
[10] The New Shorter Oxford English Dictionary, Volume 1, 4th Edition, 1993 (edited by Lesley Brown), Clarendon Press, Oxford, Page-88.
[11]International Dictionary of English, 1st Edition, 1995, Cambridge University Press, Cambridge, Page-50.
[12]Webster's New World Dictionary, 3rd Edition, 1991, (edited by Victoria Neufeldt), Webster's New World, New York, Page-59.

seen that the commonality in all the definitions is "knowledge"; it signifies that a person educated in the relevant art, who already has *apriori* knowledge in the cognitive field, regarding the outcome of later invention, reflected in the specifications[13](of the earlier invention, over which there is existing patent or the term of patent was over) or in other recognised ways, can foresee without any iota of doubt that it will happen in that particular way or it is like this. So there is nothing novelty (newness) in it-it can be anticipated very clearly and cogently, on the basis of "prior art".

III. Basic Attributes of "Anticipation" (R)

The question of "novelty"essentially involves afactual investigation. A careful consideration is required between the claimed invention, in any of

[13]**Complete specifications:** (1) Where an application for a patent (not being a convention application or an application filed under the Patent Cooperation Treaty designating India) is accompanied by a provisional specification, a complete specification shall be filed within twelve months from the date of filing of the application, and if the complete specification is not so filed, the application shall be deemed to be abandoned.

Contents of specifications: (1) Every specification, whether provisional of complete, shall describe the invention and shall begin with a title sufficiently indicating the subject-matter to which the invention relates. (2) Subject to any rules that may be made in this behalf under this Act, drawings may, and shall, if the Controller so requires, be supplied for the purposes of any specification, whether complete or provisional; and any drawings so supplied shall, unless the Controller otherwise directs be deemed to form part of the specification, and references in this Act to a specification shall be construed accordingly. (3) If, in any particular case, the Controller considers that an application should be further supplemented by a model or sample of anything illustrating the invention or alleged to constitute an invention, such model or sample as he may require shall be furnished before the application is found in order for grant of a patent, but such model or sample shall not be deemed to form part of the specification. (4) Every complete specification shall (a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed; (b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and (c) end with a claim or claims defining the scope of the invention for which protection is claimed; (d) be accompanied by an abstract to provide technical information on the invention: Provided that (i) the Controller may amend the abstract for providing better information to third parties; and (ii) if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and the following conditions.

its embodiments, and the thing that is revealed by the prior publication or use. But the larger question remains: What are its determinant factors of "being anticipated"? The answers to these questions are solely dependent on the nature and characteristics of "*a priori* knowledge, in the forms of written or oral description; this vital point needs to be explainedon the basis of next set of questions: when can it be anticipated or why is it to be anticipated? Otherwise, it will be difficult in grasping the whole gamut of "anticipation", the basic of "novelty" in any invention, deserves to be conferred patent.Over here the reliance on judicial decisions of U.K (only court of records) is pertinent because both in U.K and India, common law principles are also followed. The judgments pronounced by "courts of records" in U.K (though have persuasive values for Supreme Court of India), unfold those nature and characteristics of "anticipation".

Therefore, a perusal is perusal of the legal provisions with regard to "novelty" in the law of U.K is required. Accordingly in U.K, a patent may be granted only for an invention in respect of which the following conditions are satisfied: (a) the invention is new; (b) it involves an inventive step; (c) it is capable of industrial application; (d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A below; and references in this Act to a patentable invention shall be construed accordingly.[14] It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of-(a) a discovery, scientific theory or mathematical method; (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever; (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer; (d) the presentation of information; but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.[15] A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.[16] For the purposes of subsection (3) above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or

[14] The Patents Act, 1977, Patentability, Section 1 (1).
[15] Ibid, section 1 (2).
[16] Ibid, Section 1 (3).

any part of it.[17] The Secretary of State may by order vary the provisions of subsection (2) above for the purpose of maintaining them in conformity with developments in science and technology; and no such order shall be made unless a draft of the order has been laid before, and approved by resolution of, each House of Parliament.[18]

An invention shall be taken to be new if it does not form part of the state of the art.[19] The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.[20] The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say (a) that matter was contained in the application for that other patent both as filed and as published; and (b) the priority date of that matter is earlier than that of the invention.[21]

A clear directiveis given in Flour Oxidising v. Carr[22]: "this then is the test: if the claim is for a method of use or process, the anticipation must give 'clear and unmistakeable directions to do what the patenteeclaims to have invented"[23]. **Van Der Lely v. Bamfords**[24] is more focussed on nature of "anticipation": "If it is for an article, apparatus or substance, the qualified reader must be enabled at once to perceive and understand and be able practically to apply the discovery without the necessity of making further experiments". Very aptly, House of Lords, in**Asahi KK's Application**[25] explained: "In the case of a publication describing a new substance but not how to make it, if common general knowledge in the industry would not permit a skilled person to select or secure the starting material or make intermediate products, there has been no sufficient description of the

[17] ibid, Section 1 (4)
[18] Ibid, Section 1 (5).
[19] Ibid, Section 2 (1),
[20] Ibid, Section 2 (2).
[21] Ibid, Section 2 (3).
[22]Flour Oxidising v. Carr, (1908) 25 R.P.C. 428 (457).
[23]Flour Oxidising v. Carr, (1908) 25 R.P.C. 428 (457).
[24]Van Der Lely v. Bamfords, (1963) R.P.C. 61 (71).
[25]Asahi KK's Application, (1991) R.P.C. 485 (H.L).

invention and accordingly there is no anticipation. To satisfy these criteria, there must be an enabling disclosure."

What are emanating as features of "anticipation" are firstly; "prior disclosure" and secondly; "enabling disclosure"; these are evident not only from the specifications of earlier patent application but also other forms of "prior art", to be kept in view to ascertain or negate novelty in any invention.W.R.Cornish looks at "anticipation" as: "not infrequently, a question of anticipation centres on whether the prior document does sufficiently disclose the later invention. This may be so when the alleged anticipation is 'unintentional'; but the issue is by no means confined to such cases"[26]. **A person, educated[27]in the respective field of art (knowledge in science and technology), on the basis of (pre-existing)*a priori* knowledge, after making a comparison, while going through the "specifications" or other documents, will not anticipate the post-ri knowledge. In another words, the knowledge in claimed invention is not non-existent in the public domain and the personseducated in the relevant art know what has been done; how does it work; why it is resulting in such a way.**After this, the process to determine "inventive step" starts-the next qualifier of patentability.

These two inalienable parts attached to "anticipation" have been nicely explicated very recently by House of Lords, in **Synthon BV *v.* Smithkline Beecham Plc[28] judgment:**

> **(a).** ***Disclosure***
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> The concept of "disclosure" has been explained in two judgments of unquestionable authority. The first is Lord Westbury LC in Hill v Evans[29]: "the antecedent statement must be such that a person of ordinary knowledge of the subject would at once perceive, understand and be able practically to apply the discovery without the necessity of making further experiments and gaining further information before the invention can be made useful. If something

[26] W.R.Cornish, Page-155

[27] The author prefers to use 'educated' rather than 'skilled' in the context of novelty as related to knowledge and not application part of knowledge; while determining 'inventive step' the use of the term 'skilled' is preferred as it is pertinent to application related matter.

[28] (2005) UKHL 59.

[29] (1862) 31 LJ(NS) 457, 463.

remains to be ascertained which is necessary for the useful application of the discovery, that affords sufficient room for another valid patent.

The second authoritative passage is in General Tire and Rubber Co. v Firestone Tyre &Rubber Co Ltd[30]: "To determine whether a patentee's claim has been anticipated by an earlier publication it is necessary to compare the earlier publication with the patentee's claim. If the earlier publication discloses the same device as the device which the patentee by his claim, asserts that he has invented, the patentee's claim has been anticipated, but not otherwise. If the prior inventor's publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty. The prior inventor, however, and the patentee may have approached the same device from different starting points and may for this reason, or it may be for other reasons, have so described their devices that it cannot be immediately discerned from a reading of the language which they have respectively used that they have discovered in truth the same device; but if carrying out the directions contained in the prior inventor's publication will inevitably result in something being made or done which, if the patentee's claim were valid, would constitute an infringement of the patentee's claim, this circumstance demonstrates that the patentee's claim has in fact been anticipated.

If, on the other hand, the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee's claim, but would be at least as likely to be carried out in a way which would not do so, the patentee's claim will not have been anticipated, although it may fail on the ground of obviousness. To anticipate the patentee's claim the prior publication must contain clear and unmistakeable directions to do what the patentee claims to have invented. **A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee."**

[30][1972] RPC 457, 485-486.

> To summarise the effect of these two well-known statements, the matter relied upon as prior art must disclose subject-matter which, if performed, would necessarily result in an infringement of the patent. That may be because the prior art discloses the same invention. But patent infringement does not require that one should be aware that one is infringing: "whether or not a person is working an invention is an objective fact independent of what he knows or thinks about what he is doing".Whether or not it would be apparent to anyone at the time, whenever subject-matterdescribed in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied. The flag has been planted, even though the author or maker of the prior art was not aware that he was doing so.

Therefore, first element of "anticipation" requires prior disclosure of subject-matter of the later claimed patent, resulting in the infringement (notional) of the later patent.

(b).*Enablement*

Enablement means that the ordinary skilled person would have been able to perform the invention which satisfies the requirement of disclosure. This requirement applies whether the disclosure is in matter which forms part of the state of the art by virtue of section 2(2) or, as in this case, section 2(3). The latter point was settled by the decision of this House in Asahi Kasei Kogyo KK's Application[31].

Asahi's case was decided on the assumed facts that there had been a prior disclosure of the same invention but that neither the disclosed information nor common general knowledge would have enabled the skilled man to make it. The House therefore did not have to consider the test for deciding what degree of knowledge, skill and perseverance the skilled man was assumed to have. But the concept of enablement is used in other contexts in the law of patents "the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art".

[31][1991] RPC 485.

So, the dimension of newness or novelty, is setting out a higher order, with "enabling disclosure".

IV. "Anticipation" to Determine or Negate Novelty and its Application in India

In Monsanto Company v. CoramandalIndag Products (P) Ltd[32], Supreme Court of India, observed "anticipation" in the following way[33], after ascertaining that the emulsifying agent in Butachlorand the process of its emulsification can be anticipated, hence lacks novelty in it:

> Butachlor (CP 53619) was discovered, even prior to 1968 as a Herbicide possessing the property of nontoxic effect on rice. The formula for the Herbicide was published in the report of the International Rice Research Institute for the year 1968 and its common name Butachlor was also mentioned in the report of the International Rice Research Institute in 1969. No one patented the invention Butachlor and it was the property of the population of the world. Before Butachlor or for that matter any Herbicide could be used for killing weeds, it had to be converted into an emulsion by dissolving it in a suitable solvent and by mixing the solution with an emulsifying agent. Emulsification is a well-known process and is no one's discovery. In the face of the now undisputable fact that there is no patent for or any secrecy attached to Butachlor, the solvent or the emulsifying agent and the further fact that the process of emulsification is no new discovery, the present suit based on the secrecy claimed in respect of the active agent Butachlor and the claim for the process of emulsification must necessarily fail.**To satisfy the requirement of being publicly known (as anticipated) as used in clauses (e) and (f) of sec. 64(1), it is not necessary that it should be widely used to the knowledge of the consumer public. It is sufficient if it is known to the persons who are engaged in the pursuit of knowledge of the patented product or process either as men of science or men of commerce or**

[32]1986 SCR (1) 120

[33]Section 64(1) (e), Patents Act, 1970 (that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the, documents referred to in Section 13.

> **consumers.** The section of the public who, as men of science or men of commerce, were interested in knowing about Herbicides which would destroy weeds but not rice, must have been aware of the discovery of Butachlor. There was no secret about the active agent Butachlor as claimed by the plaintiffs since there was no patent for Butachlor, as admitted by the plaintiffs. Emulsification was the well-known and common process by which any Herbicide could be used. Neither Butachlor nor the process of Emulsification was capable of being claimed by the plaintiff as their exclusive property. The solvent and the emulsifier were not secrets and they were admittedly not secrets and they were ordinary market products. From the beginning to the end, there was no secret and there was no invention by the plaintiffs. The ingredients, the active ingredient, the solvent and the emulsifier, were known; the process was known, the product was known and the use was (also) known.

In the same way, in Bishwanath Prasad Pandey v. Hindusthan Metal Industries[34], the Supreme Court did not accept the improved devise and method for the manufacture of utensils especially shallow dishes (with more convenience, speed, safety and better finish) has novelty in it by looking at **anticipation as getting possessedbeforehand**:

> The patented machine is merely an application of an old invention[35], known for decades, for the traditional purpose of scraping and turning utensils, with a slight change in the mode of application, which is no more than a 'workshop improvement', a normal development of an existing manner of manufacture not involving something novel which would be outside the probable capacity of a craftsman. The alleged discovery does not lie outside the track of what was known before.
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> This aspect of the law relating to patentable inventions, as prevailing in Britain, has been neatly summed up in Encyclopaedia Britannica, Vol. 17, page 453. Since in India, also, the law on the

[34] AIR 1982 SC 1444.

[35] The old method of manufacturing utensils, particularly shallow dishes, was to turn scrap and polish them on some sort of headstock without a tailstock, the utensils either being fixed to the headstock by thermoplastic cement or held in the jaws of a chuck fixed to the headstock. This system was, however, fraught with risk to the workers inasmuch as the utensils used to fly off from the headstock.

subject is substantially the same, it will be profitable to extract the same hereunder: "A patent can be granted only for 'manner of new manufacture' and although an invention may be 'new' and relate to a 'manner of manufacture' it is not necessarily a 'manner of new manufacture'-it may be only a normal development of an existing manufacture." A patentable invention, therefore, must involve something which is outside the probable capacity of a craftsman-which is expressed by saying it must have 'subject matter' or involve an 'inventive step'. Novelty and subject matter are obviously closely allied. In fact, 'subject matter' is the crucial test, for which they may well be novelty not involving an 'inventive step', it is hard to conceive how there can be an 'inventive step' without novelty."

Whether an alleged invention involves novelty is a mixed question of law and fact, depending largely on the circumstances of the case. Although no absolute test uniformly applicable in all circumstances can be devised, certain broad criteria can be indicated. **Whether the "manner of manufacture" patented, was publicly known, used and practised in the country before or at the date of the patent?** If the answer to this question is 'yes', it will negative novelty or 'subject matter'. Prior public knowledge of the alleged invention which would disqualify the grant of a patent can be by word of mouth or by publication through books or other media. **"If the public once becomes possessed of an invention",** says Hindmarch on Patents "by any means whatsoever, no subsequent patent for it can be granted either to the true or first inventor himself or any other person; for the public cannot be deprived of the right to use the invention, the public already possessing everything that he could give.

Lack of Novelty in ImatinibMesylate (Beta Crystal Form)

In Novertis A G v. Union of India[36]the **apex Court very clearly explained the term "new" or "novelty" as not having been anticipated by the "prior art". Accordingly,** Supreme Court did not accept

[36]Novertis A G v. Union of India, (2013) 6 SCC 1.

IMATINIB MESYLATE (BETA CRYSTAL FORM) as new or novel as it was very much anticipatedby the “prior art” for the following reasons:

Firstly,NATCO Pharma Ltd., (one objector) had marketed a drug called VEENAT 100 in UK. A legal notice by NovertisA G was served to NATCO Pharma Ltd. by stating that it was the proprietor of European Patent (EP-A-0 564 409: Zimmermann patent) and that this patent is all about Imatinib and acid addition salts of that compound i.e. Mesylate Salt. The drug, which asNATCO Pharma Ltd. was selling, was made of active pharmaceutical ingredient of ImatinibMesylateof Zimmermann patent; it has infringed the patent. but as a result of out of court settlement, NATCO Pharma Ltd.stoppedthe marketing of the medicine:

> It would be clear that Gleevec directly emanates from the Zimmermann patent and comes to the market for commercial sale. Since the grant of the Zimmermann patent, the appellant has maintained that Gleevec (that is, ImatinibMesylate) is part of the Zimmermann patent. It obtained drug approval for Gleevec on that basis. It claimed extension of the term of the Zimmermann patent for the period of regulatory review for Gleevec, and it successfully stopped NATCO Pharma Ltd. from marketing its drug in the UK on the basis of the Zimmermann patent. Not only the appellant (Novertis A G) but the USBPA, while granting patent for beta crystalline form of ImatinibMesylate, proceeded on the basis that though the beta crystal form might not have been covered by the Zimmermann patent, **the Zimmermann patent had the teaching for the making of ImatinibMesylate from Imatinib,** and for its use in a pharmacological compositions for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease. This finding was recorded by the USBPA, in the case of the appellant itself, on the very same issue that is now under consideration.

Secondly, the apex Court, cited two articles written by Zurg Zimmermann himself, as instances of “prior art” which re-establishes that IMATINIB MESYLATE IN BETA CRYSTAL FORM, could be anticipated from original **Zimmermann patent.**

> A journal called **Cancer Research**, in its issue of January 1996, published an article under the title “Inhibition of the Abl Protein-Tyrosine Kinase in Vitro and in Vivo by a 2-

Phenylaminopyrimidine Derivative". This article was authored by several people, including Jurg Zimmermann. In this article there is a detailed discussion about the antitumoral properties of Imatinib and its methanesulfonate salt, i.e., ImatinibMesylate. In the abstract at the beginning of the article, it is stated as under: "ABSTRACT Oncogenic activation of Abl proteins due to structural modifications can occur as a result of viral transduction or chromosomal translocation. The tyrosine protein kinase activity of oncogenic Abl proteins is known to be essential for their transforming activity. Therefore, we have attempted to identify selective inhibitors of the Abl tyrosine protein kinase. **Herein we describe an inhibitor (CGP 57148 as IMATINIB IN FREE BASE FORM) of the Abl and platelet-derived growth factor (PDGF) receptor protein-tyrosine kinases from the 2-phenylaminopyrimidine class, which is highly active *in vitro* and *in vivo*.** Submicromolar concentrations of the compound inhibited both v-Abl and PDGF receptor autophosphorylation and PDGF-induced *c-fos*mRNA expression selectively in intact cells. Furthermore, anchorage-independent growth of *v-abl*- and *v-sis*-transformed BALB/c 3T3 cells was inhibited potently by CGP 57148. When tested *in vivo*, CGP 57148 showed antitumor activity at tolerated doses against tumorigenic *vabl*- and *v-sis*- transformed BALB/c 3T3 cells. In contrast, CGP 57148 had no antitumor activity when tested using *src*-transformed BALB/c 3T3 cells. These findings suggest that CGP 57148 may have therapeutic potential for the treatment of diseases that involve abnormal cellular proliferation induced by Abl protein-tyrosine kinase deregulation or PDGF receptor activation."

128. Under the heading "MATERIALS AND METHODS", it is stated as under: "**Materials.** CGP 57148 **and its methane sulfonate salt (CGP 57148B as IMATINIB MESYLATE IN NON-CRYSTAL FORM)** were synthesized by CIBA Pharmaceuticals Division, as will be described elsewhere. For *in vitro* and cellular assays, a stock concentration of 10 mM CGP 57148 was prepared in Me2SO and stored at-20oC. No significant difference in results could be seen between the two forms of CGP 57148. The form used in *in vitro* experiments is indicated in the text and legends. All *in vivo* experiments were performed using CGP 57148B."

The article goes on to discuss the *in vivo* experiments and the *in vitro* selectivity of CGP 57148 for inhibition of protein kinases: Identification of CGP 57148 as an inhibitor of v-Abl kinase. The article also discussed the *in vivo* anti-tumour activity of CGP 57148B and it states as follows: "***In Vivo* Antitumor Activity.** The maximally tolerated dose for a single p.o. or i.p. administration of CGP 57148B in BALB/c mice was >500 mg/kg. BALB/c AMuLV and BALB/c 3T3 v–*sis* cells, which were sensitive in the colony-forming assay, were used to test CGP 57148B for antitumor activity in female BALB/c nude mice. Once daily i.p. applications of 50, 12.5, or 3.13 mg/kg CGP 57148B given for 30 consecutive days resulted in a strong antitumor effect against AMuLVtransformed BALB/c 3T3 tumors (Fig. 5A). Similarly, anti-tumor experiments using v–*sis*- transformed BALB/c 3T3 cells revealed dose-dependent antitumor activity (Fig. 5B). Maximal T/C (X100%) values of 4% (AMuLVtumors) and 11% (v–*sis* tumors) were obtained when CGP 57148B was administered at 50mg/kg body weight. In contrast, CGP 57148B showed no antitumor activity against tumors derived from NIH-527*src* cells when 50 mg/kg were administered p.o. once daily for 30 days (T/C, 102%). Using the same route of application, T/C values of 7 and 22% against AMuLV and v–*sis* tumors, respectively, were obtained when 50 mg/kg CGP 57148B were given." It is further stated in the article: "CGP 57148 selectively inhibited the *in vitro* activity of the v-Ablproteintyrosine kinase and showed preferential inhibition of v-Ablautophosphorylation in cells. We have examined the specificity of CGP 57148 by analyzing its effects on signal transduction via different tyrosine kinase receptor-mediated pathways. Although the ligand-induced activation of the EGF, bFGF, insulin, and IGF-1 receptor tyrosine kinases were not affected by CGP 57148, the PDGF pathway was sensitive to inhibition by the compound. The antiproliferative activity of CGP 57148 against both v-*abl*- and v-*sis*transformed BALB/c 3T3 support the selectivity profile of CGP 57148 further." The article concludes by observing as follows: "The reported findings with CGP 57148 suggest that it may be a development candidate for use in the treatment of Philadelphia chromosome-positive leukemias. Additional potential applications

for CGP 57148 may include proliferative diseases that involve abnormal PDGF receptor activation."

An article was published in **Nature Medicine**magazine of the year 1996 under the title "Effects of a selective inhibitor of the Abl tyrosine kinase on the growth of Bcr-Abl positive cells". This article, too, was authored by several people, including Jurg Zimmermann. In this article also, there is a discussion about Imatinib as a compound designed to inhibit Abl protein tyrosine kinase.

In the face of the materials referred to above, (there is impossibility) to see how ImatinibMesylate can be said to be a new product, having come into being through an "invention" that has a feature that involves technical advance over the existing knowledge. ImatinibMesylate is all there in the Zimmermann patent. It is a known substance from the Zimmermann patent.

Lastly, it is found that the specifications of IMATINIB MESYLATE IN BETA CRYSTAL FORM, are quite identical to specifications ofZimmermann patent.The following is a glaring example (as Zimmermann inventionrelated to N-phenyl-2-pyrimidine-amine derivatives (called, "formula I" in the patentapplication), and the compounds thereof, the process for their preparation, and to theirtherapeutic uses, in the later patent application, it was expressly stated that the compounds offormula I included their respective salts):

Salt-forming groups in a compound of formula I are groups or radicals havingbasic or acidic properties. Compounds having at least one basic group or atleast one basic radical, for example a free amino group, a pyrazinyl radical or apyridyl radical, **may form acid addition salts, for example with inorganicacids, such as hydrochloric acid, sulfuric acid or a phosphoric acid, or withsuitable organic carboxylic or sulfonic acids**."Further:"Owing to the close relationship between the novel compounds in free form andin the form of their salts, including those salts that can be used as intermediates,for example in the purification of the novel compounds or for the identificationthereof, hereinbefore and hereinafter **any reference to the free**

compoundsshould be understood as including the corresponding salts, whereappropriate and expedient.

As regards the pharmacological properties of the compounds of formula I it wasstated in the application:"The compounds of formula I have valuable pharmacological properties andcan be used, for example, as anti-tumoral drugs and as drags (sic drugs) againstatherosclerosis."

"The compound according to claim 1 of the formula I, said compound being N-{5-[4-(4-Methyl-piperazino-methyl)-benzoylamido]-2-methyl-phenyl}-4-(3-yridyl)-2-pyrimidine-amine **or a pharmaceu-tically acceptable salt thereof.**"

The above-mentioned four instances, aptly give the narrative of anticipation of the ImatinibMesylate (beta crystal form). It is therefore, inferred, ImatinibMesylatein beta crystal form is not outside the Zimmermann patent and does not constitute an invention as understood in the law of patent in India, **In light of the discussions made above, it can be deduced that ImatinibMesylate(beta crystal form) is not a new product; it is not above the anticipatory power of Zimmermann patent to any extent.Zimmermann patent** itself had the capacity of teaching of beta crystal form of imatinibmesylate, not upto "imatinibmesylate" only.**ImatinibMesylate is a known substance in Zimmermann patent itself. Not only is ImatinibMesylate known as a substance in Zimmermann patent, but all its pharmacological properties are also publicly known not only from Zimmermann patent, but also from the articles published in the afore-mentioned international journals.**

V. Invention Not Patentable (Section 3 D, Patents Act)

Next point of debate cropping up in the domain of patent is section 3(d) of patents Act. The apex Court in NovertisA G v. Union of India, by upholdingsection 3(d), as representing "patentability", a concept distinct and separate from "invention", which can supersede "novelty", rejected IMATINIB MESYLATE IN BETA CRYSTAL FORM as not patentable invention: **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.** The larger questions remain to be answered: is section 3(d) a higher standard above "novelty" to be determined after ascertaining

"novelty" or is the determination of "novelty" sufficient enough to prove that it is not barred by section 3(d)?

V.I. Higher Standard of Patentability Above Novelty

It is evident from the relevant part of the judgment, that this exclusion clause sets a higher order of patentability. It implies that after fulfilling the criteria of "novelty", the claimed invention has to cross another hurdle i.e. section 3(d), for obtaining patent:

> 102. But examined in thelarger perspective of the development of the law of patent over the past 100 years andespecially keeping in mind the debates in the Parliament preceding the 2005 amendment, itwould appear completely unacceptable.There is noforce in this submission that section3(d) is a provision *ex majorecautela*. To our mind, the submission completely misses thevital distinction between the concepts of invention and patentability-a distinction that wasat the heart of the Patents Act as it was framed in 1970, and which is reinforced by the2005 amendment in section 3(d).
>
> 103. The importance of the amendment made in section3(d), cannot be under-estimated. It is seenabove that, in course of the Parliamentary debates, the amendment in section 3(d) was theonly provision cited by the Government to allay the fears of the Opposition membersconcerning the abuses to which a product patent in medicines may be vulnerable. Therefore, (there is) no doubt that the amendment/addition made in section 3(d) is meant especiallyto deal with chemical substances, and more particularly pharmaceutical products. **Theamended portion of section 3(d) clearly sets up a second tier of qualifying standards forchemical substances/pharmaceutical products in order to leave the door open for true andgenuine inventions but, at the same time, to check any attempt at repetitive patenting orextension of the patent term on spurious grounds.**

Therefore, according to apex Court, section 3(d) throws up a "**second tier of qualifying standard" or "an extension of the definition of invention" "a different standard for qualifying as "invention"or 'sets the invention threshold further higher". This challenges the very basic of patentability criteria.**

V.II. Enhanced Efficacy Test

With regard to the second part of exclusion clause, (invoked by Supreme Court), the Supreme Court is of the view that that there is no enhanced efficacy in IMATINIB MESYLATE BETA CRYSTAL FORM than what was existingin IMATINIB (including MESYLATE) for the following reasons:

> The patent application contains a clear and unambiguousaverment that all the therapeutic qualities of beta crystalline form of ImatinibMesylate arealso possessed by Imatinib in free base. The relevant extract from the patent application isonce again reproduced here:"It goes without saying that **all the indicated inhibitory andpharmacological effects are also found with the free base**, 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl) pyrimidin-2-ylamino) phenyl] benzamide, **or other cells thereof**. The present inventionrelates especially to the b-crystal form of the methanesulfonic acid additionsalt of a compound of formula I in the treatment of one of the said diseases orin the preparation of a pharmacological agent for the treatment thereto."
>
> Now, when all the pharmacological properties of beta crystalline form of ImatinibMesylate are equally possessed by Imatinib in free base form or its salt, where is thequestion of the subject product having any enhanced efficacy over the known substance ofwhich it is a new form?
>
> The highersolubility that is attributed to the beta crystalline form of ImatinibMesylate may actuallybe a property of ImatinibMesylateitself. One does not have to be an expert in chemistry toknow that salts normally have much better solubility than compounds in free base form. Ifthat be so, the additional properties that may be attributed to the beta crystalline form ofImatinibMesylate would be limited to the following:i. More beneficial flow properties,ii. Better thermodynamic stability, andiii. Lower hygroscopicity.
>
> What is "efficacy"? Efficacy means[37] "the ability to produce a desired or intendedresult". In other words, the test of efficacy would depend upon the function, utility or thepurpose of the product under consideration. Therefore, in the case of a medicine thatclaims to

[37]The New Oxford Dictionary of English, Edition 1998.

cure a disease, the test of efficacy can only be “therapeutic efficacy”. Thequestion then arises, what would be the parameter of therapeutic efficacy and what are theadvantages and benefits that may be taken into account for determining the enhancementof therapeutic efficacy? With regard to the genesis of section 3(d), and more particularlythe circumstances in which section 3(d) was amended to make it even more constrictivethan before, we have no doubt that the “therapeutic efficacy” of a medicine must be judgedstrictly and narrowly. Our inference that the test of enhanced efficacy in case of chemicalsubstances, especially medicine, should receive a narrow and strict interpretation is basednot only on external factors but there are sufficient internal evidence that leads to the sameview. It may be noted that the text added to section 3(d) by the 2005 amendment laysdown the condition of “enhancement of the known efficacy”. Further, the explanationrequires the derivative to “differ significantly in properties **with regard to efficacy**”. Whatis evident, therefore, is that not all advantageous or beneficial properties are relevant, butonly such properties that directly relate to efficacy, which in case of medicine, as seenabove, is its therapeutic efficacy.

In whatever way therapeutic efficacy may be interpreted, this much is absolutely clear: that the physico-chemical properties of beta crystalline form of ImatinibMesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy.

The position that emerges is that just increased bioavailabilityalone may not necessarily lead to an enhancement of therapeutic efficacy.

It is quite clear that**IMATINIB MESYLATE(beta crystal form)**has not yielded in any further efficacy compared to what was existing in IMATINIB IN FREE BASE FORM (including IMATINIB MESYLATE). This is due to the reason that all forms of IMATITIB, belong to same species and do not fall under different genre.Moreover, as it is “mere discovery”, it is quite conceivable that it would not be able to show any enhanced efficacy, then that of IMATINIB itself.Moreover, had there

been any "enhanced efficacy", the question of its being"novelty" would not have arisen.

VI. Some Concluding Comments

i. Section 3(D), Patents Act is Unnecessary

The first part of section (3) (d)[38]which has been invoked by Supreme Court to negate the patentability of ImatinibMesilate, (beta crystalline form)is: "**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**." While negating the claim for patent on IMATINIB MESYLATE, BETA CRYSTAL FORM, Supreme Court has invoked the said section erroneously; the truth is that the section 3(d) itself is faulty and does not in any way sets a higher standard of patentability (as second qualifierto prove invention, as has been interpreted by the apex Court) by making some inventions patentablewhile excluding some others. It is not at all an extension of the definition of invention. Neither section 3(d) of Patents Act (India) sets a second tier of qualifying standard nor does it set the invention threshold further on higher ground. **If this is so, it becomes inconsistent with WTO-TRIPS, which mandates the sovereign states to follow a uniform and minimum standard of patentability and the states are not in any way, are allowed to deviate from that threshold, by putting up a further stiff condition: "Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement[39]"**.

But, that does not necessarily mean that the decision of the apex Court is untenable as it did not endorse the claim of patent. Without invoking section 3(d) in a wrong way, the Supreme Court of India could have done it; in fact it did relying on "novelty" criteria. As the Supreme Court of India, did it on the basis of wrongful interpretation of section 3(d), by rejecting the claim of IMATINIB MSYLATE (BETA CRYSTAL FORM) as an invention, it sent a wrong message to the IPR world that India has

[38]Patents Act 1970.(Act No. 39 of 1970).

[39]PART I, GENERAL PROVISIONS AND BASIC PRINCIPLES, Article 1, Nature and Scope of obligations, Agreement on Trade Related Aspects of intellectual Property Rights, page 319.

heightened the standard of patentability criteria over and above WTO-TRIPS, by not complying with it.

Secondly, section 3(d) can never be an exception to section 2(1) (j) of Patents Act. Any 'invention' after having satisfied the tests of novelty, inventive step and industrial application, cannot be denied patent simply for failing to satisfy the tests laid down in its 3(d). This question even does not arise at all. By definition, a trifling change can never be able to live up to the threshold of "novelty". **Once an 'invention' becomes anpatentable after fulfilling the criteria of 'novelty', 'inventive step' and "industrial application", it goes without saying that it is not mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance. First of all, neither an invention cannot be treated as "mere" nor can "mere" be 'novel' in nature and in characteristic. Secondly,the word 'discovery' prefixed with new form of a known substance which does not result in the enhancement of the known efficacy of that substance, is diametrically opposite to the concept 'invention".DISCOVERY cannot be an INVENTION in any way; similarlyINVENTION can never be DISCOVRY; DISCOVERY as such will never be able to satisfy the tests of 'novelty' and others. As section 3(d) is all meant for "discovery", it will always remain outside the purview of any "invention" so far.** Though the wisdom of the parliamentarians are not being questioned (as this is only point to allay the fears from their minds to give assent to the amendment in Patents Act), but the fact remains that the criteria of "novelty", "inventive-step" and "industrial application" are fair enough to repudiate any of the trivial claims for patent. Therefore, ImatinibMesylete (beta crystaline form) is not at all 'novel' in true sense. i.e. **any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the "state of the art" under section 2(l)**. Hence, section 3(d) is a provision put in *ex abundanticautela non nocet*[40]to alley all the reasonable doubts. The preliminary purpose of section 3(d) is to

[40]Abundant caution does no harm.

prevent "ever-greening[41]" of patent and to encourage genuine inventions. It is absolutely right that the sub-section concerned becomes operational only as *ex majorecautela*[42].

Additionally, 'efficacy test' could also have come under section 2(l) of Patents Act. As, the documents, accepted as "prior art" regarding all the derivatives of N-phenyl-2-pyrimidine-amine, do not show anything novelty in IMATINIB MESYLATE BETA CRYSTAL FORM; which is why, it could not show any "enhanced efficacy" stemming from IMATINIB MESYLATE BETA CRYSTAL FORM. **Had it shown anything new or novelty, definitely it would have resulted in an enhanced efficacy. If it cannot pass the test of "novelty", it is not possible to pass the "enhance efficacy test". But if it passes the "enhanced efficacy test", without any difficulty, it also would be able to pass the hurdle of "novelty". Similarly, if any product or process does not result in "enhanced efficacy", it is absolutely impossible for it to be "novel" in nature. So "enhanced efficacy" and "novelty" are interlinked and both mutually inclusive. This is also evident that the relevant**derivative of N-phenyl-2-pyrimidine-amine **i.e. ImatinibMesylateand its various forms (including beta crystal form), is "prior art" and disclosure of all thenatural physic-chemical properties of ofImatinibMesylate(beta crystalline form) goes along with it, (which does not in any way enhance the efficacy of the so called new anti-cancer drug than that of the earlier one).So while determining the fact that whether to grant or not to grant patent, there is no need to turn to section 3(d) of Patents Act.If any medicine based on a little improvement of the basechemical materials, does not actually enhance in the "pharmaceutical efficacy" of that medicine, from the earlier one, it cannot be termed as "novel".**Therefore, section 3(d) should be deleted from the Actas for its redundancy; it cannot be even *ex majorecautela* as it deals with "discovery".

ii. Innovation Should Be Encouraged as New Form of Intellectual Property

[41]Evergreening" is a term used to label practices that have developed in certain jurisdictions wherein a trifling change is made to an existing product, and claimed as a new invention. The coverage/protection afforded by the alleged new invention is then used to extend the patentee's exclusive rights over the product, preventing competition.

[42]Out of abundant caution.

Attempt for ever-greening of patent in India, is occurring, which is a disturbing feature. One of the reasons is that there is no recognition of petty patent, a legal mechanism to encourage small or incremental innovations but just short of invention. As has been pointed out earlier as there is no "petty patent" or similar types of IPR protection India, therefore, companies or individuals are seeking to get their small innovations patented, through various means though those are not worthy to be called as inventions. Sometimes, people by indulging in manipulations or by tweaking are pursuing the wrong inventions to get patent cover. Absence of law encourages people to resort to corrupt practices. Law should not be a mechanism to encourage corruption in the society. Had there been legal provisions, the scientists or researchers could have applied for "petty patent" or similar type of IPR protection for their genuine innovations (which otherwise could not have been patented).This is one shortcoming of the legal framework (IPR) of India. A model law for IPR protection in a country must have some mechanism to motivate innovations. As far as number of patent applications (by Indians) and grantof patents are concerned, India is seriously lagging behind than countries likes USA, UK, JAPAN, CHINA. Times of India reported[43] the following truth:

> India is the top region for innovation in Asia, as per a recent report. This might seem like excellent news, till we ask how much of this innovation is truly Indian? According to Patent Office, over 70% of the patents filed in the country are by MNCs. Indian companies and academia share the remaining 30%. Currently we rank 66th on the Global Innovation Index List. That places us 41 places behind China. According to the World Intellectual Property Organisation (WIPO) India filed 1,423 international patents in 2015, US filed 57,385, Japan 44,235, China 29,846 and South Korea 14,626. On a list of the world's most innovative companies, only one Indian organisation Asian Paints ranks in the top 20 at 18. Hindustan Unilever comes in at 31. The top 10 list is dominated by the US.

The report shows a very dismal performance of Indian scientists and researchers in the global map of Intellectual Property Rights. A time has come to take some bold decisions so that in near future India can emerge as innovation capital of the world. National IPR Policy of India, should be to

[43]The Times of India, April, 25, 2017, page 10. (Can India Innovate?)R.K.Mishra and SarvSaravan).

encourage Indian scientists and researchers to invent moreat par with the developed countries. But no one can expect that at one go, Indian scientists and researchers suddenly, in large numbers will be inventing products and processes which are worthy to be patented. The country has to prepare the intellectual soil for its scientists and researchers so that one day they could compete with other developed countries. On this journey, if there is a law which will encourage innovations in the form of petty patents or similar types of IPR, it will be creating a congenial eco-system. What can be better motivating factor than insertion of required provisions in Patents Act itself (without enacting another Act) for patty patents or similar types of IPR, for those small innovations which cannot fulfil all the patentable criteria. As Indian scientists or researchers are not in a position now to come up with huge numbers of patents, thereby, at first, they should get accustomed with innovations. Let Indian scientists and researchers apply their intelligentsia and engage resources to come up with more innovative products or process in the country. While doing this, little by little they will start inventing products and processes which can fulfil patentability. Unless, innovations are recognised, they will not be able to raise their intellectual minds and augment capacity to the next higher level.

iii. [**Innovative Patent[44]of Australia (along with some exceptions) are worthy to me mentioned**]:

> Innovative step[45]: (4) For the purposes of this Act, an invention is to be taken to involve an innovative step when compared with the prior art base unless the invention would, to a person skilled in the relevant art, in the light of the common general knowledge as it existed (whether in or out of the patent area) before the priority date of the relevant claim, only vary from the kinds of information set out in subsection (5) in ways that make no substantial contribution to the working of the invention; (5) For the purposes of subsection (4), the information is of the following kinds:(a) prior art information made publicly available in a single document or through doing a single act;(b) prior art information made publicly available in 2 or more related documents, or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art would treat them as a

[44]Patents Act 1990, (Act No. 83, 1990) Australia.
[45]Section 7 (4), (5), (6).

single source of that information.(6) For the purposes of subsection (4), each kind of information set out in subsection (5) must be considered separately.

Patentable inventions for the purposes of an innovation patent[46]: (1A) Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim:(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and(b) when compared with the prior art base as it existed before the priority date of that claim:(i) is novel; and(ii) involves an innovative step; and(c) is useful; and (d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.(2) Human beings, and the biological processes for their generation, are not patentable inventions.

iv. Likely to the innovative patent of Australia, Japan also has a utility model to encourage small innovations[47]. The purpose is to encourage devices by promoting the protection and the utilisation of devices[48]:

Conditions for Utility Model[49]: A creator of a device that relates to the shape or structure of an article or combination of articles and is industrially applicable may be entitled to obtain a utility model registration for said the device, except when the following applies:(i) the device was publicly known in Japan or a foreign country, prior to the filing of the application for a utility model registration therefor;(ii) the device was publicly worked in Japan or a foreign country, prior to the filing of the application for a utilitymodel registration therefor; or(iii) the device was described in a distributed publication, or a device that was made publicly available through an electric telecommunication line in Japan or a foreign country, prior to

[46]Part 3-Validity, Division 1, section 18.
[47]Utility Model Act (Act No. 123 of 1959).
[48]Article 1. (device means the creation of technical ideas utilising the laws of nature, relating to the shape or structure of an article or combination of articles, and thereby, to contribute to the development of industry.
[49]Article 3 (1).

the filing of the application for a utility model registration therefor.(2) Where, prior to the filing of the application for a utility model registration, a person ordinarily skilled in the art of the device would have been exceedingly easy to create the device based on a device prescribed in any of the items of the preceding paragraph, a utility model registration shall not be granted for such a device notwithstanding the preceding paragraph.

v. To have the IPR protection, in Australia, the innovation must be at first "novel" and then it must show "innovative step", a quality just short of "inventive step". In tune with Australia, India can have a innovative patent regime. The first criterion is all about simple "novelty'. As far as the second criteria is concerned, it is to be ascertained that the claimed innovation makes some incremental contributions, though it was obvious, but very much surprising (to a person skilled in this art) as it was not thought of earlier to put in place and not acted on it.In the same way, India can also have a utility model, as new form of IPR, the way Japan grants.The criteria for granting "utility model" is that the shape or structure of an article or combination of articles, has not been described in the "prior art", not publicly known and obviously has not been worked out. All that it emphasises is nothing but simple "novelty". But the second criteria are just short of inventive-step; **to a person ordinarily skilled in the art of the device or structure, it would not have been exceedingly easy for that person in creating the device or structure.** It therefore, implies that the new device or structure though obvious, but it was tough for any ordinary skilled person in innovating the new device or structure (not exceedingly easy). It does not necessarily mean that India must replicate those AUSTRELIAN MODEL or JAPAN MODEL. India can have its own *sui generis*IPR regime to encourage and protect innovations-with "quasi-novelty"wherein the specific "a priori knowledge" regarding product or process as the case may be, was not in use, though there has been disclosure (in the form of coverage), but it was not enabling in nature from any form of "prior art". Second part of the criteria is to be an "innovative step" likely. Or in the alternative, simple "novelty" without considering "inventive-step"at all, may be a ground for granting "petty patent" or similar type of IPR in India. **The second avenue is quite convenient, because the**

term "innovate" entails something new (therefore novel in nature) sans "inventive step". Both "innovation" and "new or novel" are synonymous or similar in nature and content. The term INNOVATE is therefore (i). to change (a thing) into something new; (ii). to introduce (something) for the first time[50]; (iii). to bring in or introduce novelties; (iv). to bring in (something new) for the first time[51].Hence, only on the basis of "newness"or "novelty" in the field of science and technology, without taking recourse to "innovative-step" a petty patentor innovative patent can be granted, in India.

vi. Defence Mechanism is a Hindrance to Encourage Innovation

In an interview, Patrick Kilbride, Executive Director of International Intellectual Property at US Chamber of Commerce's Global intellectual Property Centre[52] highlighted some of the loopholes with India's IPRs:

> The only statement in that area of statute is that we are already TRIPs compliant. That does not send a good message to innovative industries. On the other hand, in terms of recognition of positive contribution of intellectual property towards investment in the innovative spaces it sends a different message. That's why I say it comes across as ambivalent. We think TRIPs by itself is insufficient to launch India into the group of countries that are leading the global knowledge economy. It is insufficient to drive large scale innovation and investment in India. It would take two times TRIPs to put India into that tier of countries. We are looking at how we can encourage unilateral adoption of strong IP rights so that it is a sovereign policy choice and not a concession in a free trade agreement. The case we are trying to make is that intellectual property is not something you do for your trading partner in order to gain access. It is something that you invest in for the strength of your own economy for the sake of domestic innovation. In many ways we would like to get out of the trade agreement space and focus on countries acting unilaterally to

[50]The New Shorter Oxford English Dictionary, Edited by Lesley Brown, Volume I, Clarendon Press, Oxford, 1993, Page 1373.
[51]The Oxford English Dictionary, (Second Edition), Volume-VII, Clarendon Press, Oxford, (prepared by J.A.Simpson& E.S. Weiner, 1991, Page-997.
[52]India is Trips Compliant; Our Response is Who Cares? The Times of India, April, 07, 2017 at page 7.

build their own legal infrastructure for innovation. We want it to be organic.

What Mr. Patrick Kilbride is advocating, partially there is truth in it. In this journey of making IPR regime robust and dynamic, USA also has a long way to go, either by amending section 102 of US Code, which does not recognise "prior use" in any other country except USAor by fully stopping bio-piracy (sometimes in the name of bio-prospecting)where there is no benefit-sharing with the holders of traditional knowledgeof Indian medicinal plants. Keeping own country above any change, will not augur well in this globalised world. However, in India there has to be a change in the mindset of the policy makers. The approach so far has been to adopt a 'defence mechanism'. This mechanism negatively teaches to take a decision keeping in view to prevent the developed countries from taking any advantage from the system. Which country would or might take the advantage of a country's law and national policy that should not be the determining factor for a country's march towards development.Determining factor for a country's law and national policy as far as IPR is concerned, should be whether at present or in future will the country itself be able to take the full advantage of it or not. From this perspective, the recognition for petty patent or innovative patent for innovative products and processes, will go a long way in encouraging innovations. This negative approach cannot be a policy of a country which enriched with rich cultural heritage like India, the country which now is trying to build up its fortune on knowledge based economy and wants to become a global leader by 2022. The country must be confident with its intelligentsia and capability to win over other developed countries in the field of INTELLECTUAL PROPERTY RIGHTS.Unless, Indian intelligentsia is forcefully or otherwise, pushed into in innovating, no one can expect that suddenly they would come out with big inventions. Before, the intelligentsia are cognitively prepared in inventing, a preparation of soil is needed. So recognition of petty patent or innovative patentis the preparation of that intellectual soil. It is very surprising as to why was petty patent or innovative not recognised earlier? Was there any national and international conspiracy by some vested interested groups, to keep the Indian intelligentsia dwarf or incompetent? So that Indian economy could never be able to be knowledge based and as the Indian intelligentsia will not be growing to invent, it would be easier to control the entire market.How long time will this negative protection mechanism continue? Unless, scientists or

researchers are given an eco-system to encourage innovative ideas, nothing positive can happen in this country. **And what can be more encouraging than recognitionof IPR over innovations (something short of invention) as new form of intellectual property right-a preparation of the country's intelligentsia for bright future,for making the fundamental base of country's economy in knowledge.**

vii. No Place of Petty Patent in National IPR Policy, India

While pointing out the significance of strong and effective, IPR protection in a country like India, in the introductory part, the National IPR Policy[53] stated:

> Creativity and innovation have been a constant in growth and development of any knowledge economy. There is an abundance of creative and innovative energies flowing in India. The evolution of the film and music industry; the contribution of the Indian pharmaceutical sector in enabling access to affordable medicines globally and its transformation to being the pharmacy of the world; richness and versatility of the Indian systems of medicines such as Ayurveda, Unani, Siddha and Yoga; the advances made in the Indian space programme and the pioneering role of our scientists in keeping it cost effective; these are but a few examples of these energies.
>
> While India has always been an innovative society, much of the intellectual property (IP) created remains unprotected both on account of lack of awareness and the perception that IP protection is either not required or that the process to obtain it is unnecessarily complicated. The rationale for the National IPR Policy lies in the need to create awareness about the importance of intellectual property rights (IPRs) as a marketable financial asset and economic tool.
>
> India has robust IP laws and a strong IP jurisprudence. The legal framework does reflect the underlying policy orientation and national priorities, which have evolved over time, taking into account development needs and international commitments. An all-encompassing IPR Policy will promote a holistic and conducive

[53]National intellectual Property Rights Policy (2017), Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, Government of India.

ecosystem to catalyse the full potential of intellectual property for India's economic growth and socio-cultural development, while protecting public interest. Such a policy will nurture the IP culture, guiding and enabling all creators and inventors to realize their potential for generating, protecting and utilizing IPRs which would contribute to wealth creation, employment opportunities and business development. This policy shall weave in the strengths of the Government, research and development organizations, educational institutions, corporate entities including MSMEs, start-ups and other stakeholders in the creation of an innovation conducive environment.

The policy lays down seven objectives for the accomplishment of which the nodal Ministry or Department of Governments is expected to undertake some steps. It is very unfortunate that the recognition of innovative or petty patents (as new form of IPR to encourage and protect innovations) is not figured out in those seven objectives of India's National Intellectual Property Rights Policy. Therefore, there is no question of its being evident in the steps to be undertaken. Unless and until, India enacts a law to grant petty or innovative patents (without enacting a law also it is possible if, some new sections are inserted in the existing Patents Act) then whatever may be the VISION or MISSION STATEMENT of recently framed National IPR Policy, (India), it would remain partially discontented.