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MARCH 19, 2008

Respected Prime Minister,

**COMMENTS ON DRAFT MANUAL - 2008 OF PATENT PRACTICE &
PROCEDURE PUBLISHED BY PATENT OFFICE**

1. The Patent office has put on the website 368 pages of Draft Manual of Patent Practice & Procedure for implementing the Patents Act, 2005.
2. The principal Act of 1970 has been drastically revised to comply with TRIPS Agreement and Paris Convention. Thus the new law of 2005 has been in operation for just a little over 2 years. The Patent office practice under the new law is still to evolve. In any case the practice has to be within the framework of statute law and all questions concerning patentability, publication and examination of patent application, the procedure governing the grant of patents etc. are all solely within the purview of and regulated by the provisions contained in the Act and Rules.
3. The Powers of the Controller are also set out in section 73(3) and (4) and sections 77 to 81 of the Act, and those specifically referred to in respect of certain proceedings under the Act. Neither the Controller nor the Central Government has any authority or sanction of law to publish a Manual of the kind put on the website.
4. **Irrelevance of the Manual** The document itself declares that "The Manual does not constitute rule making and hence do not have the force and effect of law. Statements made in the Manual are not in themselves an authority for any action by an officer of the Patent Office." It also says that "While the manual may be regarded as a hand book, it does not impose any particular line of action and may not be quoted to that end." The Patent office thus recognizes the absence of any legality for the document and disowns any authoritative nature to the contents of the document.
5. The Manual seems to be the off shoot of MOU between India and USA on Bilateral co-operation on IP, when viewed in the light of the following statement in the press release issued by the US Patent Office: "Among the activities designed to strengthen the work of both offices, the USPTO will help train Indian patent and trademark examiners, develop education material for the examiners and produce a manual on patent practice for use by Indian examiners and the public...." Ironically, USPTO itself came for criticism by US Supreme Court for granting frivolous patents.
6. Containing as it does, interpretation of various provisions of the law by the Patent Office (which is within the domain of Courts), the official manual (despite disclaimer about authenticity) will provide a fertile ground for litigation and controversy in the interpretation of the legal aspects (vis-à-vis the Act/Rules and the Manual), tending to tilt the balance in favour of the mighty MNCs, who have the resource to litigate.
7. For example, Section 3(d) [under Chapter IV of Inventions not Patentable] and some of the examples cited as being eligible for patents (as in Para 4.5.3 of Manual) would cause immense damage to the legislative intent. Sec.3(d) has been

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deliberately incorporated by parliament based on the EC directive 2004 to prevent evergreening. It is common knowledge that MNCs use all sorts of legal maneuvers and loopholes to keep extended monopoly for their expired patents by effecting minor and trivial modifications to the basic invention, to prevent competition and keep the generics off the market. The law in section 3(d) is a small attempt of the legislature to curb and counter the practice of "ever greening of patents" (or perennial patenting, whereby the product is secured legal protection even after patent expiry) by refusing to recognize such claims, and explicitly restricting generally the scope of patentability to "new inventions" - i.e where "the subject matter has not fallen in public domain or that it does not form part of the state of the art." [section 2(1)(l)].

8. It has been held by the Supreme Court in Bishwanath Prasad Padhey Shyam v. M/s. Hindustan Metal Industries [AIR 1982 SC 1444], 'obviousness' has to be strictly and objectively judged." SC has held that "in order to be patentable an improvement on something known before...should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an inventive step". If what is stated in paragraph 4.5.3 of the Manual is applied, it will lead to absurdity and help patent seekers to bypass the law easily. More importantly, such a proposition will be in total disregard of the law laid down by the Supreme Court in the aforesaid case. The principle of law as approved by SC is applicable at all times, as it is fundamental to the Patents law.

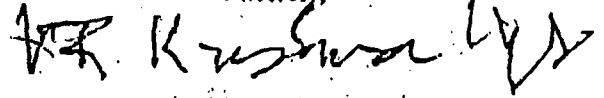
In my opinion the present 2008 draft manual should therefore be wholly scrapped.

(d) L. Krishna Iyer

For your convenience I have enclosed an eight page explanatory note.

With Kind Regards,

Yours sincerely,


(V R KRISHNA IYER)

Ms 28/3

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MARCH 19, 2008

MOST IMMEDIATE

Respected Prime Minister,

My attention has been drawn to the draft manual of 2008 Practice & Procedure published by the Patent Office. A cursory glance of the documents shows that the manual may create more problems for the users and the administration.

I would urge upon you to leave the latest Patents Act 2005 and rules to be interpreted by the judiciary. The Patent office should merely administer the law given to them by the parliament and not enter into casual interpretations of the law through a manual which has no legal or binding effect.

I have enclosed a brief summary along with an explanatory note of eight pages for your kind perusal.

With Kind Regards,

Yours sincerely,

कायस्थ एव उद्योग मंत्री कार्यालय

C & I M's Office

डातार नं/Dy. No.

दिनांक/Date

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29/3/08

V. R. Krishna Iyer
(V. R. KRISHNA IYER)

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MARCH 19, 2008

MOST IMMEDIATE

Respected Prime Minister,

Manual of Patent Practice & Procedure

The Patent Office has put on the web site a document, supposedly to be a draft Manual of Patent practice and procedure, for the implementation of the Patents Act, 1970 (as amended by Parliament) and the Patents Rules, 2003, inviting comments from the public.

The basis of Patents law:

The provisions of the Patents Act, 1970 (as amended by Parliament from time to time) and provisions of the Patents Rules, 2003 (as amended from time to time), only govern the law relating to Patents in India. Consequently, all questions concerning patentability, publication and examination of patent applications, the procedure governing the grant of patents, grant of compulsory licence on various grounds prescribed, revocation of patents for non working or in public interest, international arrangements etc. are all solely within the purview of and regulated by the provisions contained in the Act and Rules. Thus it is entirely regulated by law made by Parliament or by the Central Government by virtue of powers of delegated legislation expressly conferred on it by law. The powers of the Controller are also set out in section 73(3) and (4) and sections 77 to 81 of the Act, and those specifically referred to in respect of certain proceedings under the Act.

Section 159, which confers powers on Central Government to make Rules, has not empowered the Central Government to make Rule with respect to the preparation and publication of a Manual of Patent practice and procedure. There is also no provision in the Act which confers any authority on the Controller himself to make a Manual governing all the aspects of the law concerning Patents, which is innocuously called Manual of Patent practice and procedure. In fact the law does not contemplate anything to be done in the context of execution of the Act, outside its framework. The statute on the subject of Patents is comprehensively dealt with in great detail by the

Any provision
to take over
instructions
on Act & Rules
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provisions of the Patents Act and the Rules made thereunder. Even the aspect of submitting a Report of the Controller with respect to the execution of the Act is specifically authorized under section 155.

Irrelevance of the Manual:

The document, which is put on the web site, on.....is quite voluminous and consists of 368 pages. Before studying this huge document and offering worthwhile comments/suggestions within a short period of time, viz. on or before 25th March, 2008 the fundamental questions are whether it is necessary to have such a document and if so, its relevance and true legal effect.

The document itself declares that "The Manual does not constitute rule making and hence do not have the force and effect of law. Statements made in the Manual are not in themselves an authority for any action by an officer of the Patent Office." It also says that "While the manual may be regarded as a hand book, it does not impose any particular line of action and may not be quoted to that end." The Patent office thus recognizes the absence of any legality for the document and disowns any authoritative nature to the contents of the document. Further, the statement implies that -

- It does not attempt to ensure uniformity of practice in the Patent Office, which is a sine qua non in the administration of the Act through different branch offices under one common Controller of Patents, by explicitly recognizing that an officer may adopt "any line of action". It is well known that pharmaceutical companies aggressively pursue and secure patents for drugs with incremental innovations. In this respect, the MNCs, by filing 2 to 3 patent applications each for existing molecules with minor changes, effectively misuse to their own advantage the practice of independent functioning of the branch offices without a co-ordinated single system of processing (press report of Mint dt.14.8.07).
- The Manual document cannot be quoted or relied upon by an affected person before the Appellate Board or superior courts in any proceedings, though it is a public document.
- Though the principal Patents Act was enacted in 1970, and has been in operation from 1972, the Patent office did not consider it essential to bring out any Manual or Handbook so far.
- The principal Act has undergone considerable revision in the wake of TRIPS Agreement on 3 occasions, the last being in 2005, and the important provisions of the law (which are just a little over 2 years old) are yet to be tested before superior courts, except on one occasion when a case came up before the Madras High Court in the context of section

3(d). It is thus premature to think in terms of bringing out a "Manual of Patent Office Practice", when indeed the practice itself is still to evolve on various matters. The practice develops over the years in the light of the working of the Act and decided cases on points of law before High Court or Supreme Court.

The Manual of Patent office practice is therefore to be flawed on its threshold, as being premature, and without any meaning or relevance to the public or its potential users.

Evidently, the Manual is the off shoot of MOU between India and USA on Bilateral co-operation on IP, when viewed in the light of the following statement in the press release issued by the USPO:

"Among the activities designed to strengthen the work of both offices, the USPTO will help train Indian patent and trademark examiners, develop education material for the examiners and produce a manual on patent practice for use by Indian examiners and the public...."

If the emergence of the Manual is as a result of such bilateral efforts of the two countries pursuant to the MOU, it is all the more regrettable to see the Patent office in India being guided by examiners of US Patent office, who are known to allow all sorts of claims for patents for inventions and discoveries, best suited to meet the needs of their business enterprise. It will not be surprising, if the end result of the Manual turns out to be tilted in favour of Patentees, rather than public interest, unless there is judicial intervention in contested cases. When the US Patent office practice is itself under criticism by no less than the US Supreme Court for allowing frivolous patents, it is a pity that India should seek their guidance in formulating the Manual of practice on Indian law.

Well established & Sound legal system in India:

The Patents law in India has been in operation as early as from 1911 and with the evolution of statute law, the case law has also steadily developed. With India's accession to TRIPS Agreement and Paris Convention for Protection of Industrial Property, the statute law and its administration is also in complete harmony with each other. The judiciary has also become well versed with the subject of IPR, as is evident from the recent judgment of the Madras High Court on the Novartis case, where the Court rejected the demand of Novartis to issue guidelines to Examiners in the matter of administration of the law under section 3(d).

In the light of all these factors, what is the purpose and need for a Manual of Patent office practice & Procedure. Whom is it going to help? Is it the public or the Patent Examiners or the IPAB or judiciary which is ultimately responsible for the interpretation of the provisions of the Act and Rules. It may lead to unintended consequence by making a fertile ground for litigation and controversy in the interpretation of the legal aspects (vis-a-vis the Act/Rules and the Manual), tending to shift the balance in favour of the mighty MNCs, who have the resource to litigate.

The Draft Manual & its impact on new section 3(d):

Instead of conducting a microscopic analysis of the draft Manual in all its aspects, it will be sufficient if, by way of example, the most important provisions of the law as contained in section 3(d) is considered, with a view to appreciate difficulties the Manual may create.

Section 3(d) of the Patents Act enacts in clear terms the following as not inventions:

- the mere discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance; or
- the mere discovery of any new property or new use for a known substance; or
- of the mere use of a known process, machine or apparatus, unless such known process results in a new product or employs at least one new reactant.

The law is further clarified explicitly to state that "salts, esters, ethers" etc. and other derivatives of known substance shall be considered to be the same substance "unless they differ significantly in properties with regard to efficacy".

Mere discovery of new property is not patentable invention (e.g. a mere discovery of a new property of the substance such as aspirin for use of treatment of some other disease cannot be considered patentable); New use for a known substance is also not patentable. In other words, 2nd or 3rd use for a known substance cannot be allowed. Thirdly, a mere use of a known process is not patentable, unless such known process results in a new product or employs at least one new reactant.

It is common knowledge that MNCs use all sorts of legal maneuvers and loopholes to keep extended monopoly for their expired patents by effecting minor and trivial modifications to the basic invention, to prevent competition and keep the generics off the market. The law in section 3(d) is a small attempt of the legislature to curb and counter the practice of "ever greening of patents" (or perennial patenting, whereby the product is secured legal protection even after patent expiry) by refusing to recognize such claims, and explicitly restricting generally the scope of patentability to "new inventions" – i.e. where "the subject matter has not fallen in public domain or that it does not form part of the state of the art." [section 2(1)(l)].

The expression "invention" [in sec.2(1)(j)] should be clearly relatable to a basic new product or process and exclude those claiming with minor modifications and incremental changes. This would find support from the studies and recommendations by the UK Commission on IPR.

The Parliament has also defined "Pharmaceutical substance" as meaning "any new entity involving one or more inventive steps." [2(1)(ta)]. The expression "inventive step" is again defined to mean "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." [2(1)(a)].

As was held by the Supreme Court in *Bishwanath Prasad Radhey Shyam v. M/s Hindustan Metal Industries* [AIR 1982 SC 1444], the 'obviousness' has to be strictly and objectively judged." In the same case, the apex court held that 'it is important to bear in mind that in order to be patentable an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an 'inventive step'. The law of patentability is thus unambiguous in that a claim for improvement 'must independently satisfy the test of invention or an inventive step'.

The draft Manual gives specific examples of patentable and non patentable subject matter under section 3(d), which is totally uncalled for and beyond the jurisdiction of the Patent Office. The broad principle of patentability as decided by the Supreme Court in the above case is universal and applicable at all times and in all cases. Further, every case would need to be examined and decided with regard to its own merits; and with reference to the law as may evolve and the subject-matter of the claim or claims in that case. Casual citation of examples may, far from clarifying the law, cause difficulties in its administration, and even to Courts in reaching a correct conclusion in a given case.

By way of illustration, in paragraph 4.5.3, the Manual states as follows:

"The examiner makes comparison with regard to properties or enhancement of efficacy between the known substance and the new form of known substance. In case the new form is further converted into another new form, the comparison is made between the already existing form and another new form but not between the base compound and another new form."

Assume that the known substance is "Compound X". A patentee could reveal a new "Form A" of the known substance, which would have very little or no enhancement of efficacy over compound X. A few months down the line, he can come up with another new form "Form B". He now has to show enhancement of efficacy against Form A only, which in any case is inferior, and not over compound X. This will lead to absurdity and help patent seekers to bypass the law easily.

More importantly, such a proposition will be in total disregard of the law laid down by the Supreme Court in the aforesaid case.

Patent Office Handbook:

The Manual of Patent Office Practice & Procedure, should refrain from giving or set down any authentic guidelines about the interpretation of the provisions of law, which is exclusively within the domain of the judiciary. The illustration given above will show the difficulties that may arise.

If the Government is so keen to bring out a Manual, besides giving the complete provisions of the Act and Rules, should merely cite the applicable case law or quote the legal 'principles' as laid down by the Court in a given case, so that the law is left to be evolved in its own course. Such a Manual should be for the purpose of ensuring uniformity of practice among the examiners and other officers exercising the functions of Controller, which should be the supreme concern of the Patent Office through the Manual. On the contrary the Manual seems just to do the opposite by stating that 'it does not impose any particular line of action'. It will be abdication of responsibility by the Controller, if the official Manual (as it indicates) is to be interpreted as giving a free hand to the delegated functionaries in their work. It will do violence to the statutory mandate of sub-section (3) of section 73, which enacts that the officers 'shall discharge under the superintendence and directions of the Controller' such functions as he may authorize them to discharge.

It is important to remember that any official Government publication is authentic and could be relied upon by the users. Then how is it open for the Patent Office to say that the Manual "does not impose any particular line of action and may not be quoted to that end." In fact, in terms of section 117E, the Controller is bound to appear before the Appellate Board, as and when required, in any legal proceeding in which any question relating to the patent office practice is raised. The Manual would come so handy to a litigant to bind the Controller by his own words. On the other hand, if the Government feels confident that the statements made in the draft Manual are consistent with the law and can stand judicial scrutiny, why not make them all as part of the Patents Rules to give it a legal effect. Such a comprehensive document, which may be taken as codifying the 'practice of the patent office' may serve the interests of public and the users and check arbitrariness of officials of Patent Office, ensuring uniformity of practice. But it is not possible to do so, without express delegation of power to the Central Government through an amendment of the Patents Act.

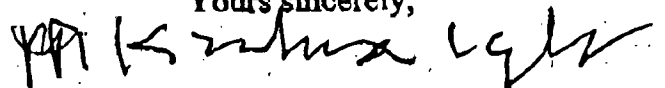
Admittedly the document has no legal basis nor can be relied on by anyone in respect of any proceedings under the Act & Rules for its authenticity. What is the use of such a public document, except to create more controversies and litigation.

It is suggested that if at all necessary to publish a Manual, it should be modeled on what the Patent Office had been doing for over a century by publishing a 'Patent Office Handbook', updated through revised editions from time to time.

The present draft Manual should therefore be wholly scrapped and in its place a new edition of Patent Office Handbook may be brought, if it is considered so necessary. The absence of a Manual or a Patent Office Handbook will not do any harm, but a Manual of this nature will do more harm than good.

With Kind Regards

Yours sincerely,



(V R KRISHNA IYER)

DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 31 March 2004

amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal by the Commission⁽¹⁾,Having regard to the Opinion of the European Economic and Social Committee⁽²⁾,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽³⁾,

Whereas:

(1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use⁽⁴⁾, codified and consolidated in a single text the texts of Community legislation on medicinal products for human use, in the interests of clarity and rationalisation.

(2) The Community legislation so far adopted has made a major contribution to the achievement of the objective of the free and safe movement of medicinal products for human use and the elimination of obstacles to trade in such products. However, in the light of the experience acquired, it has become clear that new measures are necessary to eliminate the remaining obstacles to free movement.

(3) It is therefore necessary to align the national laws, regulations and administrative provisions which contain differences with regard to the basic principles in order to promote the operation of the internal market while realising a high level of human health protection.

(4) The main purpose of any regulation on the manufacture and distribution of medicinal products for human use should be to safeguard public health. However, this objective should be achieved by means which do not hinder the development of the pharmaceutical industry or trade in medicinal products in the Community.

(5) Article 71 of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products⁽⁵⁾ provided that, within six years of its entry into force, the Commission was required to publish a general report on the experience acquired as a result of the operation of the marketing authorisation procedures laid down in that Regulation and in other Community legal provisions.

(6) In the light of the Commission's report on the experience acquired, it has proved necessary to improve the operation of the marketing authorisation procedures for medicinal products in the Community.

(7) Particularly as a result of scientific and technical progress, the definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products for human use. In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, the definition of 'medicinal product' should be modified so as to avoid any doubt as to the applicable legislation when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products. This definition should specify the type of action that the medicinal product may exert on physiological functions. This enumeration of actions will also make it possible to cover medicinal products such as gene therapy, radiopharmaceutical products as well as certain medicinal products for topical use. Also, in view of the characteristics of pharmaceutical legislation, provision should be made for such legislation to apply. With the same objective of clarifying situations, where a given product comes under the definition of a medicinal product but could also fall within the definition of other regulated products, it is necessary, in case of doubt and in order to ensure legal certainty, to state explicitly which provisions have to be complied with. Where a product comes clearly under the definition of other product categories, in particular food, food supplements,

⁽¹⁾ OJ C 25 E, 26.3.2002, p. 216 and OJ C ... (not yet published in the Official Journal).

⁽²⁾ OJ C 61, 14.3.2003, p. 1.

⁽³⁾ Opinion of the European Parliament of 23 October 2002 (OJ C 100 E, 11.12.2003, p. 353), Council Common Position of 29 September 2001 (OJ C 297 E, 9.12.2003, p. 41), Position of the European Parliament of 17 December 2003 (not yet published in the Official Journal) and Council Decision of 11 March 2004.

⁽⁴⁾ OJ L 311, 28.11.2001, p. 67, Directive as last amended by Commission Directive 2003/63/EC (OJ L 159, 27.6.2003, p. 46).

⁽⁵⁾ OJ L 214, 21.8.1993, p. 1. Regulation repealed by Regulation (EC) No 726/2004 (see p. 1 of this Official Journal).

8) Article 10 shall be replaced by the following:

Article 10

1. By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.

A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subparagraph shall also apply if the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation.

The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

2. For the purposes of this Article:

(a) "reference medicinal product" shall mean a medicinal product authorised under Article 6, in accordance with the provisions of Article 8;

(b) "generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of

an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

3. In cases where the medicinal product does not fall within the definition of a generic medicinal product as provided in paragraph 2(i) or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided.

4. Where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

5. In addition to the provisions laid down in paragraph 1, where an application is made for a new indication for a well-established substance, a non-cumulative period of one year of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.

6. Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products;

9) the following Articles shall be inserted:

Article 10a

By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I. In that event, the test and trial results shall be replaced by appropriate scientific literature.

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December 7, 2007


Dear Parliamentarian,

Salutation to you as I seek to invoke your spirit of nationalism on a matter of compassionate moment to the millions of our countrymen who struggle to defend their right to life and health by may be priced out of the pharmaceutical market or starved of life-saving drugs if any dilution of patents act 2005 is made. I have pleasure to enclose a ONE PAGE summary for your kind perusal with an explanatory note comprising SEVEN PAGES for your in-depth study. The country must be saved from conquest through patents strategized by MNCs. We must be allergic to avoidable infiltration of giant corporates (wolves in sheep's clothing) who care more for market occupation and maximum profit under patented baloney, rather than common peoples health and social survival.

Alas, MNCs who corner global pharma have nobody to be burnt nor soul to be damned.

With kind regards,

Yours sincerely,


(V.R. KRISHNA IYER)

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(Former Judge, Supreme Court)

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December 7, 2007

DILUTION OF PATENTS ACT WILL BE DISASTROUS

I address this letter to you, to share with you my serious concern and alert you about the concerted move of the powerful drug lobby of the western world, to get the Patents law diluted to meet their own ends.

In brief, the issues involved here are -

- Parliament has rightly laid down the patentability criteria, as per trips standards, which the drug lobby wants to further dilute
- Validity of Section 3(d) inserted by Parliament has been upheld by Madras High Court, which is now sought to be nullified. The Government council Sri. V.T. Gopalan Additional Solicitor General has submitted before the Madras High Court in the Novartis case that the Government has rejected the Mashelkar panel report.
- Plea before High Court for issuing guidelines to Patent Examiners to interpret section 3(d) was rightly rejected by High Court. Interpretation of the provisions of law is solely within the jurisdiction of Courts. Neither a subordinate legislation, nor executive instructions or a departmental Procedure Manual, can ever attempt to over ride the provisions of law made by Parliament.
- If the drug lobby is only genuinely interested in protecting an improvement in the original patented invention, referred to as 'incremental innovation' by Mashelkar panel, it is available by means of 'Patent of addition' under section 54. no change is required to the law.
- Section 3(d) is designed to prohibit camouflaged invention and perennial patenting. This provision which has received judicial endorsement, has become a model for other countries. Even the US Supreme Court has called for redefining 'obviousness' and the US Congress is debating a Reforms Bill to counter the abusive practice.

The enclosed seven page explanatory note will highlight the seriousness of the issues, so that you can effectively block any attempt in parliament to dilute the safeguards made in the Patents Act. Needless to say the matter is no less serious than the Indo-US Nuclear agreement, over which Parliament and the country was agitated. I am confident, with your active intervention, the supreme will of Parliament shall not be allowed to be subverted.

With high regards,

Yours sincerely,

V R Krishna Iyer

(V. R. KRISHNA IYER)

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Dilution of Patents Act will be disastrous

Patentability criteria:

The criteria for patentability is the heart and soul of any patent law and is fundamental to the system.

Article 27 of TRIPS, which prescribes norms and standards for member countries, lays down three patentability criteria, namely,

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- novelty,
 - inventive step;
 - and industrial applicability.
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It is to be noted that TRIPS agreement did not think it necessary to define the expression 'novelty' or 'inventive step' but left it to the contracting parties to define. The requirements of patentability under the Indian law are perfectly within the broad ambit of 'novelty' and 'inventive step' as universally recognized. Indeed such a view derives support from Art.31(1)(i) of TRIPS, according to which an invention must "involve an important technical advance of considerable economic significance" to qualify even for grant of a compulsory licence, let alone patentability.

Further Member States have the freedom to legislate, guided only by the principles and objectives set out in Art.7 and 8 of TRIPS Agreement, which, read with the DOHA Declaration, provides sufficient flexibilities to member States to frame the Patents law of developing countries, like India, to suit its special needs, particularly in the area of patents for drugs and pharmaceuticals.

Doha declaration explicitly recognizes that :

“TRIPS does not and should not prevent members from taking measures to protect public health; TRIPS can be and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and to promote access to medicines for all”.

The Indian Parliament did not avail of the freedom or the flexibility given by the Doha declaration, in framing the provision in section 3(d), but merely took care to clarify the law appropriately just to ensure that patents are not granted to inventions, which are basically lacking in novelty.

Growing concern in US

There is growing concern in the US itself about dubious patents being granted and serious efforts are being made to bring about domestic reforms in the US Patent system. In particular, the proposed reform aims at exactly what India has done, viz. to disallow patents for inventions which are not ‘new’ in the true sense of the term, and modify the rules so as to prevent the abuse of the patent system by ‘perpetuating’ patent rights beyond the 20 year term of patent. The proposals for reform of US Patents law include -

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- laying down more rigorous standards for determining whether an invention is obvious or novel, and by redefining the term ‘obviousness’
 - permitting third parties to submit additional prior art upon publication of patent applications, to reduce possibility of granting patents to inventions that are obvious
 - providing for an effective and expeditious post grant opposition system
 - providing for cheaper and faster means of reviewing patent validity than the current costly and one sided court procedures
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Another significant move in the US is ‘to set up a process to re-evaluate patents’ of such dubious nature which have already been issued.

United Kingdom:

Again, in the United Kingdom the thinking is no different. In this connection, some of the key recommendations contained in the CIPR Report, for adoption by developing countries (as set out in Chapter 6), which are interesting from our point of view, include –

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- avoid patenting of new uses of known products
 - make use of strict patentability and disclosure requirements to prevent unduly broad claims in patent applications
 - exclude totally from patentability diagnostic, therapeutic and surgical methods for the treatment of humans and animals
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How can Government of India be unaware of these trends of world opinion in the matter, to succumb to the pressure of MNCs in the pharmaceutical sector?

Important step taken by India:

In a global economy, there is continuous cut throat competition among corporate giants who are vying with each other to secure their market share, and in this the IPR is the key instrument. As if 20 year term of patents is not enough, attempts to perpetuate the monopoly for marketing their products through patents become their natural choice. In this respect, marginal improvements and innovations, without any substantive inventive step, become the subject matter of patent claims.

In his work: "Truth about Drug Companies – How they deceive us and What to do about it", Mr. Marcia Angell, M.D., former Editor in Chief of the New England Journal of Medicine, says thus:

"Once upon a time, drug companies promoted drugs to treat diseases. Now it is often the opposite. They promote diseases to fit their drugs. Nearly everyone experiences heartburn from time to time. The remedy used to be a glass of milk or an over the counter antacid to relieve the symptoms. But now heartburn is called "acid reflux disease" or "gastroesophageal reflux disease" and marketed, along with the drugs to treat it, as a harbinger of serious esophageal disease – which it usually is not. As a result, in 2002, Prilosec was the third best selling drug in the world (Nexium had not yet had a chance to replace it) and its competitor Prevacid was seventh."

Such is the case of exploitation of people by the drug companies, and in this they will stoop to any level.

While there is no doubt that patent system is the best way to encourage inventions, India recognized as early as in 1970 that it was equally necessary to provide safeguards against possible abuses of the system. Thus in 2005, while adopting patent reforms to respond to the obligations under TRIPS, India was conscious of the need to continue the balance between public interest needs and providing a sound system of Intellectual Property Protection, in accordance with international norms and standards.

A significant step taken by India is the introduction of a provision as in section 3(d) in the Patents Amendment Act to **curb and counter the practice of "ever greening of patents" (or perennial patenting whereby the product is secured legal protection even after patent expiry) by refusing to recognize such claims, and explicitly restricting the scope of patentability only to "new inventions" – i.e where "the subject matter has not fallen in public domain or that it does not form part of the state of the art."** [section 2(1)(l)].

The amended provision in section 3(d) has worked effectively in preventing the grant of patent to Novartis in respect of a cancer drug GLIVEC (where the main patent is to expire soon), which was found to be a case of attempted ever greening of patent. Novartis not only appealed against the decision of the Patent Office, but also challenged the validity of the amendment law. While admitting the appeal to be heard by Intellectual Property Appellate Board, the court rejected the plaintiff's argument about the validity of the amended law or that there should be guidelines to guide the Controller.

Dr.Mashelkar Committee's findings:

The report submitted by the Technical Group headed by Dr.Mashelkar, to study the two issues concerning section 3(d) and scope of patentability, came in for severe criticism and as a national shame and embarrassment, because the report was found to have reproduced portions of a UK based report on patents in favour of multinationals. At the request of embarrassed Mashelkar, the report was treated as withdrawn, and there was persistent demand from all sides that he shall not be allowed to rewrite the report. In any case, the report is not worth the paper on which it is written and needs to be confined to the record room.

In the intervening time, the issues referred to the Committee have got resolved by themselves to a large extent through judicial process in the Novartis case and many countries in the world adopting the provisions of the Indian law. The same subject has received judicial notice in the US Supreme Court which has advocated redefining 'obviousness' to prevent grant of frivolous patents in the US. The seriousness of 'bad patents' is felt so strongly in the US, there is a uniform approach in that country at all the three levels, namely, legislature, judiciary and the executive.

This is exactly what has been done by the Parliament in India in the recent enactment through the Patents Amendment Act of 2005.

Does Govt. of India now plan to nullify Parliament's law?

Mashelkar panel's report is now a dead issue. Still strangely, the Government is reported to be using the very same report and is reported to have 'accepted' the panel's key recommendation to encourage "incremental innovation." What is incremental innovation? It is a term unheard of in the history of Patent law anywhere in the world; neither it is used in the TRIPS text nor in the Paris Convention. The only criteria for patentability are those referred to above, viz. novelty, inventive step and industrial applicability. The Patents Act clearly defines all these and other relevant expressions comprehensively in Section 2. Further the law explicitly elucidates what are not regarded as inventions within the meaning of the Act.

According to Mashelkar report, it appears that 'incremental innovations' are sequential developments that build on the original patented product and may be of tremendous value in a country like India'. In other words, such inventions are more in the nature of an improvement or modification of an invention disclosed in the main invention. If that is so, section 3(d) is not an obstacle. Indeed, the existing Act already contains provision for protecting such inventions by means of 'Patents of addition', under section 54. Are the MNCs unaware of the law? But they would not wish to talk about it, because that will not enable them to perpetuate the monopoly position, which is their basic objective. Section 55 enacts that the life of patent of addition will be equal to that of the patent for the main invention, or so much

thereof as has not expired. Such an explicit law does not serve their purpose.

Another seriously disturbing news is that, the Government is working to evolve norms to guide patent examiners understand what 'constitutes enhancement of the known efficacy of a substance', on the ground that without such guidelines in place most 'incremental inventions' are unlikely to be accepted for patents by the patent office. With section 3(d) in place in the statute book, how can the Government ever think of evolving norms and guidelines for Patent examiners to allow patents in respect of claims for patents, which are clearly not allowable [rather forbidden] under the law, and thus actively subvert the law passed by Parliament? Indeed the Madras High Court rejected the plea of Novartis for giving guidelines to patent examiners on section 3(d). Patent examiners are required to discharge their functions in accordance with the law as contained in the Patents Act and in the light of judicial interpretations from time to time. The Controller and other officers are bound by judicial rulings.

It is not a question whether the so-called 'incremental invention' is important or not, but whether it could come within the prescribed patentability criteria. In any case, the only course through which such protection, if at all, should be made available [for 'improvements to the main invention'] is by grant of 'patent of addition', as provided under section 54 and certainly not as an independent patent.

Patent Manual:

The Patent Office, which is reported to be working on publishing a Manual of Procedure for the administration of Patents Act, should refrain from giving or set down any authentic guidelines about the interpretation of the provisions of law, which is exclusively within the domain of the judiciary. So the Manual at best can state the law as laid down by the Court in a given case, so that the law is left to be evolved in its own course. Such a Manual is for the purpose of ensuring uniformity of practice among the examiners and other officers exercising the functions of Controller. Its purpose is not to supplement the law or become a subordinate legislation in the nature of rules made by the Central Government under powers of delegated legislation. The distinction must be clearly respected in the production of Manual of Procedure. It should thus be modelled on what the Patent Office had been

having for over a century titled as 'Patent Office Handbook', updated through revised editions from time to time.

Appeal to Government and Parliament:

The amended provision of the law in section 3(d) has received judicial approval as of now. There is no doubt that the law will stand the test of time as it does not transgress TRIPS and is within the framework of international norms. It is, therefore, that several countries are adopting the Indian model in their patent legislations. Indeed, as Government is aware, even the US has woken up to realities after being flooded with bad patents, and through judicial interventions urging US Government to take measures to redefine 'obviousness' and to prevent the trend of perennial patenting, by misusing patents law.

The MNCs in the drug industry would continue to exert pressure, through all the means available to them, on the Indian Government to scrap the provision in section 3(d), or at least subvert it in a way that suits the MNCs through the so called 'guidelines' which they advocate (and which have been rejected by the High Court). It must be resisted at all costs, in the interest of public and in the interest of development of a sound system of patent protection in India. The purpose and scope of Section 3(d) is to deny patents in respect of inventions which lack substantive novelty and patentability, which is the core of the statute.

For securing due legal protection to improvements in inventions already patented, for what they call as 'incremental inventions', the provisions already available in the Patents Act, vide section 54, should only be used. For this purpose, no dilution of law in section 3(d) is called for.

With Kindest Regards,

Yours sincerely,



(V R KRISHNA IYER)