**National Working Group on Patent Laws** 

[Centre for Study of WTO Issues]

D-86/3, Okhla Industrial Area, Phase - 1, New Delhi - 110 020 (India) Phones: 4052 - 1796, Fax : 4052 - 1795 <wgkeayla@del6.vsnl.net.in>

FATRON
JUSTICE V.R.KRISHNA IYER
Former Judge
Supreme Court (India)

CHAIFMAN Dr. NITYA NAND Former Director Central Drug Research Institute

CO-CHAIRMEN
Mr. S.P. SHUKLA
Former Member
Planning Commission (India)
Frof. MUCHKUND DUBEY
Former Foreign Secretary
Govt.of India
Prof. ASHOK PARTHASARTHI
Former Secretary to
the Govt. of India

CONVENOR
Mr. B.K. KEAYLA
Former Commissioner of
Payments, Govt. of India

CONVENOR CORE GROUP Or. RAJEEV DHAVAN Senior Advocate Supreme Court (India)

CÖ-CÖNVENORS
Mr. DINESH ABRÜL
CSIF: Scientific Workers' Assn.
Dr. BISWAJIT DHAR
Indian Institute of Foreign Trade
Prof. B.S. CHIMIII
Jawahar Lal Nehru University
Dr. AMIT SEN GUPTA
Delhi Science Forum

MEMBERS Mr. BALRAJ MEHTA Senior Journalist Prof. ARUN KUMAR Jawahar Lal Nehru University Mr. PRAFUL BIDWAI Senior Journalist Dr. K. SATYANARAYANA Indian Council of Med. Res. Dr. MIRA SHIVA All India Drug Action Network Mr. K. ASHOK RAO National Confn. of Officers Asan, of P.S. undertakings Mr. N.H.ISRANI Indian Drugs Mfrs. Assn. Dr. N.N. MEHROTRA Academy of Young Scientists Mr. K.G.CHATTERJI Forum of Scientists Engineers & Technologists Dr. S.N. CHATURVEDI Technical Consultant Ms. USHA MENON Delhi Science Forum

Mr. AMITAVA GUHA National Campaign Committee

on Drug Policy

Mr V. Ravi, Controller General of Patents, Designs and Trade Marks Boudhik Sampada Bhawan, S.M. Road, ANTOP Hill, Mumbai-400037.

Dear Sir,

We have examined the Draft Manual of Patent, Practice and Procedure. Our comments are attached (Annexure-I).

्रिट्ट ग्रहानियंत्रक कार्नि रक्ताराम

of Controller General

हान्स वं/Diery No......

Date: 16.4.2008

We have in the meanwhile, received a copy of letter dated March 19, 2008 (Annexure-II) addressed to the Prime Minister of India by Justice VR Krishna Iyer, Former Judge, Supreme Court. We have also examined this letter and we fully agree with the suggestions contained in his letter. We fully support the views expressed about the irrelevance of the Manual.

While examining the Manual, we find that the same contains a large number of case laws emanating from foreign countries. Most of these case laws are quite old and are based on the laws of those countries' practiced during that relevant periods. Even our Patents Act of 1911 was based upon philosophy not relevant for our country's interest. The original Patents Act of 1970 was a legislation based upon the national aspirations of our people and the objective of self reliance. There are a few case laws during the period our original Patents Act 1970 was in operation. Keeping these factors in view, it would not be proper to approve the proposed Manual which is practically based on the case laws which are not relevant at the present juncture. This is another argument against the Manual and as such we reiterate that there is no need of the proposed Manual.

There may be a need of preparing a booklet briefing our examiners on various aspects of the patent system. Such a briefing booklet could be for internal use in the Patent Office. The examiners should basically be guided by the stipulations in various sections of our Amended Patents Act 1970 and the Patents Rules of 2003.

Thanking you,

Yours sincerely,

(B.K. Keayla)

Encls: As above.

AnnI

## COMMENTS ON DRAFT MANUAL OF PATENT PRACTICE AND PROCEDURE.

CHAPTER I: INTRODUCTION

Page 11, para 1.2.12

1. The Patents (Amendment) Act of 2002 did not incorporate "provision to protect biodiversity and traditional knowledge" Section (3) in fact, dealt with exclusion from patentability and as such this should be treated as deleted.

CHAPTER III: PATENTABLE SUBJECT MATTER

Page 21, Para 3.1 Introduction

Sub-para 3.1.1

2. Criteria No. (i) provides that the invention "must be novel". This may be expanded by adding "having unrelated features".

Para 3.2 Novelty of Invention

- 3. Sub para 3.2.1 In the last line, the words "and has unrelated features" be added after the word "domain".
- 4. Para 3.3.7: In fifth line after the word "essential", the words "and unrelated" may be added.

CHAPTER IV: INVENTION NOT PATENTABLE:

Page 58, para 4.5.3

5. The last two lines are bit confusing. It should be clearly indicated as to what the scope of comparison will be. Whether the base compound or the new form or both will be compared with another new form. This para is quite important and should be formulated in a clear and expanded manner.

Page 72, para 4.10.1

6. This para indicates that any microorganism discovered from the nature is not patentable. According to section 3 (j) of the amended Patents Act, 1970, microorganism is patentable. Thus there is a need to define as to what kind/form of microorganism would be patentable. There is a need to define the patentability scope of microorganism which can be covered under this section.

We would suggest that only genetically modified microorganism should be patentable. Since this modified microorganism perform various activities, only specific and each activity should be separately covered by the process patent only.

The technology of modifying the microorganism to genetically modified microorganism could also be covered by the process patent.

It is extremely important to deal with this aspect more explicitly and in a detailed manner.

It is unfortunate that this matter has remained unresolved even after an assurance given on the floor of Parliament.

### CHAPTER V: APPLICATION FOR PATENT

Page 118, para 5.8.11 Unity of Invention,

7. In sub-para (a), the word "specially" may be substituted by the word "specifically"

Para 5.9: Sufficiency of disclosure.

8. Sub para 5.9.2 deals with patent application where there is mention of biological material. This para needs to be expanded to provide for the requirement of agreement with the biological material supplier and agreement reached with him about benefit sharing.

CHAPTER VII: OPPOSITION PROCEEDINGS TO GRANT PATENT

Page 178, para 7.1.2 : Proceedings under pre-grant opposition.

9. Sub para (viii) provides for rejecting representation against granting of patent or allowing grant of patent. The decision of the Controller should have logical conclusion of allowing appeal to either party against the decision of the Controller.

Page 185 para 7.2.2, sub para (i)

10. In the names of persons having interest in the subject matter of the patent, the name of the person/organization which unsuccessfully contested the pregrant opposition may also be incorporated.

CHAPTER IX: PROVISION OF SECRECY OF CERTAIN INVENTIONS.

Para 9.3 Prohibition to apply Patent for invention outside India.

Page 215 sub para 9.3.3

11. In addition to the invention relevant for defence purpose and atomic energy, the invention relating to biodiversity material of India should also be incorporated for taking permission..

Page 226, para 10.12 Term of Patent

Para 10.12.1

12. Reference to patent term which had not expired on 20th May, 2003 under Patents (Amendment) Act 2002, should be clarified as "process patent" instead of "patent" which may not be mistaken as 'product patent'.

CHAPTER XIV: SURRENDER AND REVOCATION OF PATENTS

Page 252, para 14.2.5 Revocation of patent for non-working

13. Even if the patented product is not worked by the patent holder and the first compulsory licence holder, it is logical that additional compulsory licences should be issued to other interested enterprises. A notification could be issued inviting other enterprises to work the patent. A sub para to this effect could be added to para 14.2.5.

There have been instances in the past when supplies of critical material/component were blocked at the instance of the concerned foreign government for important concerns. The instances of blocking of critical materials are after the atomic experiments at Pokhran. Under these circumstances, it would be appropriate for the government/Controller to revoke the relevant patent. It would be a challenge for the domestic enterprises to research and produce that particular material blocked by the foreign patent holder or the concerned government. This important aspect could also be added in this para.

CHAPTER XVIII: WORKING ON PATENT AND COMPULSORY LICENCE AND REVOCATION

Page 292, para 18.2.4

sub para (f) reads as follows:

14. "Whether the applicant has made efforts to obtain a licence from the Patentee on reasonable terms and conditions and whether such efforts have not been successful within a reasonable period construed as the period not oridinarily exceeding a period of six months as the Controller may deem fit (Section 84.6)"

The compulsory licence under section 84 (6) is to be granted if;

- i) the reasonable requirement of the public with respect to the patented invention has not been satisfied;
- ii) the patented invention is not available to the public at a reasonably affordable price;
- iii) the patented invention has not worked in the territory of India.

The Patent holder which may be belonging to a foreign country will not entertain any ground reasoning about the three conditions mentioned above. There is a misplaced requirement to be posed by the applicant to the patent holder. He will not accept the contention that he was abusing his patent right. In fact, these grounds aught to be submitted to the Controller and not the patent holder. It is no doubt that this is the requirement of Section \$4 (6) of the Patent Act, it may be relevant to provide that the applicant should submit the relevant grounds to the Controller and then the Controller should refer these grounds to the patent holder. Controller can wait for six months to decide the case i.e. the time stipulated for response by the patent holder in the relevant section of the Patents Act 1970.

Page 293, para 18.2.7: Revocation of Patent for non-working (S.85)

Sub para (1) provides that if the compulsory licence holder has not worked the patent for two years, patent can be revoked on application either by the Central Government or any other person interested after expiry of two years. In case the first compulsory licence holder has not worked the patent, it will be logical to notifying the failure and invite other enterprises to file applications for grant of compulsory licences. Thus, the public interest of working the patent will get satisfied better.

#### Page 295 para 18.2.11

16. The circumstances for extreme urgency could also be due to environmental causes viz. pollution of air, pollution of water or pollution of soil. It would be desirable to incorporate these important circumstances for notification by the Government the circumstances of extreme urgency and grant of compulsory licences immediately under Section 92 (3).

#### Para 18.3, Section 92 (A)

- 17. provides for "compulsory licences for export of patented pharmaceutical products in certain exceptional circumstances"
- Para 18.3.3 provides that the provision in Section 92(A) has been introduced to address the public health problems of the countries having insufficient or no manufacturing capacity in the pharmaceutical sector.

The important aspect of this provision is that the enterprise which has received such an export order will not be able to meet the export demand if that enterprise is not already manufacturing the product under compulsory licence for domestic demands. That enterprise will have to develop technology to manufacture that product and the same may take one or two years to develop the technology and stabilize the production and the product. Additionally, the other important aspect is that the small export demand will not be viable if that enterprise is not already manufacturing the relevant product. This is the practical problem.

Under the above circumstances, it would be relevant to point out that Article 31(b) of the TRIPS Agreement provides for granting of compulsory licences for commercial activity on commercial terms and conditions. If this provision is implemented, it would facilitate the domestic enterprise to produce patented product predominantly for the domestic market and also will have possibility to meet the export demand, even when the export orders are small.

Another aspect could also be considered that the enterprise which supplies the patented product meeting the export order under compulsory icence should be automatically granted compulsory licence for meeting the domestic demand also.

## V. R. Krishna Iyer (Former Judge, Supreme Court)

Fax and Phone: 0484-2370088
"SATGAMAYA"
M. G. ROAD, ERNAKULAM,
KOCHI – 682 011

Email: <u>satgamaya@dataone.in</u> Website: <u>www.vrkrishnaiyer.org</u>

MARCH 19, 2008

Perpected 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 colely within the purview of and regulated by the provisions contained in the Act and Fules.
- 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. <u>Irrelevance of the Manual</u> 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 Eflateral 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 MICs, 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

deliberately incorporated by parliament based on the EC directive 2004 to prevent evergreening. It is common knowledge that MPICs use all sorts of legal maneuvers and loopholes to beep 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)(1)].

- 8. It has been held by the Supreme Court in Bishwanth Prasad Radhey 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 ac approved by SC is applicable at all times, as it is fundamental to the Patents law.
- 9. In my opinion the present 2008 draft manual should therefore be wholly scrapped.

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

With Kind Regards.

Yours sincerely,

(V Ř KRISHNA IYER)