THE PATENTS ACT, 1970

THE PATENTS (AMENDMENT) ACT, 2005

AND

THE PATENT RULES, 2003

As amended by THE PATENTS (AMENDMENT) RULES, 2016

Section 15

In the matter of Patent Application No. 1098/KOL/2010 dated 30/09/2010

Applicant Name: ITC LIMITED Hearing Date : 05/11/2018

FACTS

The hearing was offered on non-compliance of the Section 3(b) of The Patents Act and obtaining NBA permissions. An opportunity of hearing under Section 14 of The Patents Act was offered to the applicant through office letter dated 04/10/2018.

The hearing notice had the following objections,

Para 1. Non-Patentability u/s 3

1. The alleged invention is non-patentable under section 3(b) of patent Act which states that "An invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment"

Para 2. Other Requirement(s)

1. As the invention, as disclosed in the specification, uses biological material from India(Tobacco leaf,), prescribed permission from the competent authority(National Biodiversity Authority) should be obtained and a declaration to that effect should be made in relevant paragraph of Form-1. If the declaration in Form-1 regarding the use of biological material from India is cancelled out by the applicant and the specification also states that the source and geographical origin of the biological material is not from India, the specification should be amended by way of incorporation of a separate heading/paragraph at the beginning of the description that the biological material used in the invention is not from India and should clearly specify the country of source and geographical origin of the same. Also list out the biological materials of the description along with their geographical origins.

Formal Requirement(s)

1. The phrase 'about' should not be used when ranges are given.

In subsequent to the hearing held on the said date, the applicant's agent has submitted their written submissions on 20^{th} November, 2018. The amendments such as merging of claims 11,18,23 and 25 in the claim 1, were carried out .

The applicant's agent has contended in the written submission for the objections raised in the above said objections,

For the Para No.1 of the hearing notice said above, it was justified only in terms of the usage of tobacco and not on harmful effects of using tobacco. Also in addition the applicant's agent emphasized on the problem to be solved and highlights the technical features of the invention. As it is already agreed and acknowledged that the purported patent document has already met the patent criteria such as novelty, inventive steps and industrial applicability, the submission on this aspect is not taken for the impugned order.

It is to be noted that the tobacco in any form is harmful to human health or life due to the presence of various constituents which are classified as carcinogen, respiratory toxicant, cardiovascular toxicant, reproductive or development toxicant and addictive etc.

The applicant's agent thyself admitted the usage as low dose wherein the low dose usage was not supported as that it will not cause cancer or any other related problems as said in the above paragraph.

The section 3(b) very clearly states "an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment"

Further it is to be noted that the alleged patent document teaches that the tobacco forms an essential feature and hence the application or attraction of Section 3(b) in the alleged case is inevitable. Also the applicant's agent failed to prove that such usage is harmless and can be exempted from Section 3(b).

For the Para No.2, of the hearing notice above, instead of seeking permission from the National Biodiversity Authority (NBA), it was contended and the applicant's agent justified, however, it's an act of serious violation of the requirement under Section 6(1) of The Biological Diversity Act, 2002.

Also it is to be noted that neither the Patent Office nor the Applicant is the appropriate authority to decide whether the alleged invention can be exempted from the requirements of NBA. It is to be noted that the office has been communicating the Department of Atomic Energy and also Defense whenever the inventions involve materials pertaining to Atomic Energy Act and also Defense.

CONCLUSION

Hence it is hereby decided based on the above facts with the help of the Patents Act and the Biological Diversity Act and concluded that subject matter of this alleged invention represented vide claims 1-22, are not patentable for not meeting the requirements of Section 3(b) of The Patents (Amendment) Act 1970 and also for not obtaining the NBA permission.

ORDER

In view of the above facts and findings, the undersigned, under the provisions of the Act, refuses to proceed further with this application for the patent right and hence, the same is **refused under Section 15** of The Patents (Amendment) Act, 2005 for not meeting the requirements of Section 3(b) of The Patents (Amendment) Act, 2005.

Dated this 13th June, 2019

(M.R.MANIVASAKAM)

A. J. Henrich Ba

ASST. CONTROLLER OF PATENTS & DESIGNS