Responses
to the issues raised in the
Discussion Paper
on the
Utility Model

Indian Pharmaceutical Alliance

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PREFACE

The Department of Industrial Policy and Promotion, Ministry of Commerce has published a Discussion Paper in May 2011 on Utility Models. The paper has identified 11 issues for resolution and has invited public comment.

The Indian Pharmaceutical Alliance (IPA) appreciates the consistent efforts of the Department of Industrial Policy and Promotion to invite opinions and give all responses serious consideration before finalizing policy.

The Discussion Paper has provided a comprehensive and thoughtful backgrounder that facilitates informed deliberation. The IPA has given the matter its careful consideration and is of the view that the utility model is not appropriate for pharmaceutical products and processes. The comments of the IPA in this document are therefore mainly restricted to this aspect and do not address all the issues listed in the Discussion Paper.

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Issue for discussion

1. Does India need a Utility Model Law?

2. What should be the scope of protection of such a law? Should it be restricted to mechanical devices?

IPA comments

The 'spirit of *jugaad*' illustrated by over 100,000 ideas, innovations and traditional knowledge in the database of the National Innovation Foundation may argue for the utility model for mechanical devices for the reason admirably summarized in the Discussion Paper:[1]

"However, in a resource constrained economy like ours, it could be argued that these minor technical inventions which frugally use local resources in a sustainable manner need to be encouraged by providing a legal framework for their protection and commercial exploitation. Such useful, low cost and relatively simple innovations which create new mechanical devices or contribute to the optimal functioning of existing ones may have commercial value only for a limited time period, before they are replaced by other products or rendered redundant by change of technology."

The crux of this reasoning however cannot be extended to pharmaceuticals for the reasons discussed below.

Negation of Sec 3(d)

Unlike other categories of products and processes, the grant of patent monopolies for pharmaceuticals represents a complex trade-off between the imperatives of encouraging innovation and ensuring access to affordable medicine. The Patents Act as amended in 2005 achieves this balance via Section 3(d) by ensuring that discoveries of new forms that do not enhance efficacy are not granted patents. Thus even if a discovery is of 'new' substance (ie novel), it is not entitled to a patent unless enhancement in efficacy is demonstrated.

The intent of this provision is to safeguard against "evergreening" of patents which results in lengthening the period of monopoly and delaying the entry of affordable generics. Section 3(d) effectively raises the threshold of inventiveness as far as pharmaceuticals are concerned.

The enactment of a utility model would undo Section 3(d). Unlike the case of mechanical devices, there is no evidence to suggest that innovation in the pharmaceutical industry would be given a fillip by the introduction of the utility model. On the contrary, it is reasonable to apprehend that the utility model will have the potential to delay affordable generics and adversely affect public health by granting patents without scrutiny or by doing away the requirement of inventiveness.

Global markets

The whole intent of the utility model is to promote 'low cost and relatively simple innovations' mainly aimed at the local market, though foreign markets are not ruled out.

Pharmaceutical products are aimed at diseases or conditions that are generally prevalent globally. India is a major supplier of generic products to the world.

[1] DIPP, Utility Models, Discussion Paper, p 4, para 10.

Utility protection is not available for pharmaceuticals in many countries of the world. The introduction of utility protection in India has the potential to deny Indian exporters such markets as manufacture in India would not be possible in the face of a utility patent though similar protection may not be available in foreign markets.

Subject matter exclusion in utility models

Scholars have sounded several cautions in introducing utility models. For example, Uma Suthersanen's study quoted in the Discussion Paper as arguing for utility models has categorically recommended that:[2]

"Should it still be felt that policy considerations necessitate the introduction of a utility model system in a particular country, it is recommended that the following essential features be considered:

- **Subject matter of protection:** The utility model law should comprise a detailed list of excluded subject matter which must mirror the exclusions under the patent law. Moreover, it is worth considering excluding some types of invention as dictated by public policy such as chemicals or pharmaceuticals or biological material or substances or processes"

The exclusion of specified subject matter in utility models is common. For example, China, Japan, Korea, Mexico, Taiwan and many other countries appear to narrowly limit the subject matter in their utility models and pharmaceuticals are not covered.[3]

The potential for abuse

One example serves the purpose of illustrating the potential of abuse of the utility model in relation to pharmaceuticals.

Polymorphs of a chemical substance have identical chemical properties but differ in terms of the arrangement of atoms in their crustal lattice – they are thus another form of the substance, prohibited by Section 3(d) unless they result in an enhancement of efficacy.

In the US for example, patents for novel polymorphs are routinely granted and generic companies routinely discover new polymorphs not to infringe such patents. These are not patentable in India and only generic companies which seek to export to the United States invest in such effort.

The utility model may well permit the grant of protection in India of polymorphs because they are novel. Such utility patents would not result in the availability of more efficacious products in India, but would primarily be intended to block the manufacture of the generics for export. The net result may thus only be the abuse of patent monopoly.

Issue for discussion

5. What should be the nature of linkages between this law and the existing Patents Act? How do we ensure that the existing Patents Act, which is a bulwark against the ever greening of patents, remains undiluted?

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2 Suthersanen, Uma: Utility Models and Innovation in Developing Countries, ICTSD and UNCTAD, Geneva, February 2006, p 38. Available at http://www.unctad.org/en/docs/iteipc20066_en.pdf

3 DIPP, Utility Models, Discussion Paper, pp 11-13, para 31.

6. What legislative route should be adopted? Should a separate law to protect utility models be enacted? Or should the Patents Act be suitably amended? Or should the Designs Act be amended?

IPA comments

Should a utility model be decided upon, other than for pharmaceuticals, it would be desirable to consider enacting a separate legislation for this purpose.

As rightly pointed out in the Discussion Paper, since the utility model is primarily aimed at minor innovations from the SME sector, it must be through a legal framework that is not demanding, quick, cheap, and simple.[4]

The application of the Patents Act would not meet this objective and exclusions to simplify the procedure for utility models would be cumbersome and detract from achieving the goal of simplicity for protection under the utility model.

It is therefore recommended that a separate legislation be considered for utility models.

[4] DIPP, Utility Models, Discussion Paper, pp 4-5, para 10.