

# Indian pharma cos fear, novelty won't pay here

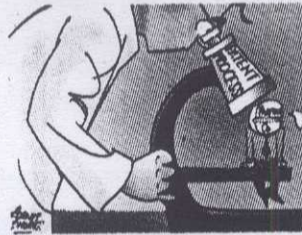
## Long negative list of patentability discouraging research and development

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Domestic pharma majors fear that the new negative list on patenting substances will discourage indigenous research and development (R&D). Since they are far from launching a new chemical entity of their own, some of India's largest pharma companies are focusing on novel drug delivery systems (NDDS) for the time being.

As the name suggests, these are alternative methods of delivering a drug. If a drug exists in the form of a tablet, an injectable, a slow release tablet or an oral solution would be considered an NDDS and vice versa. NDDS are either same molecules or modified molecules or assortment of molecules.

The problem is Indian patent law has a long negative list of "frivolous modifications" that are ineligible for patents. These include: salts, esters,



ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substances.

According to the law, these modifications will be deemed to be the same substance, unless they differ significantly in efficacy.

While WTO's trade related intellectual property rights (TRIPs) accord defines an invention as 'patentable' if it is 'new', 'capable of industrial application' and 'involves an inventive step', the government tightened the definition of these terms in December under pressure from the Left.

Companies like Ranbaxy, Biocon and Nicholas Piramal which are working on NDDS fear that the patents' controller could rule that an analogue (a modified molecule) is akin to a derivative and deny the patent on those grounds.

Ranbaxy has applied for three patents and Biocon a clutch of patents for oral insulin. In other major pharma markets, patents are usually granted for analogues and derivatives. ♦