



INTELLECTUAL PROPERTY SPOTLIGHT

INTRODUCTION

We are pleased to present the latest edition of our IP Law page, sharing important updates, key developments, and practical insights on Intellectual Property, all tailored to help you stay updated in the field of Indian Patent Law.

Curated by our IPR Law Practice Group, the page is to keep you updated about the latest developments in this dynamic field.

MADRAS HIGH COURT RULES PROCESS TO PRODUCE ANTIBODIES IN GENETICALLY MODIFIED ANIMALS PATENTABLE

In a significant ruling, the Madras High Court in *Kymab Limited v. Assistant Controller of Patents & Designs* has held that the process of producing antibodies in genetically modified animals is patentable and does not fall under the exclusions of Section 3(i) of the Indian Patents Act, 1970.

The plaintiff sought a patent for a process involving the generation of antibodies in non-human mammals, specifically incorporating a human immunoglobulin (Ig) variable region. The invention also proposed a non-human animal model for antibody production. However, the Indian Patent Office rejected the application, arguing that the invention constituted a method of treating animals—a subject matter deemed non-patentable under Section 3(i).

Section 3(i) of the Patents Act excludes two categories of processes from patentability:

a. Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic, or other treatment of human beings; and

b. Any process for a similar treatment of animals to render them free of disease, increase their economic value, or enhance the economic value of their products.

The Patent Office contended that the invention fell under the second category. However, the Court disagreed, offering a detailed analysis of the claimed subject matter and Section 3(i). It highlighted three key findings:

1. The process does not involve treating non-human mammals (such as mice) for any therapeutic purpose.
2. The invention's purpose is not to enhance the economic value of the animals themselves, such as by selling transgenic mice at a premium.
3. The antibodies produced by the genetically modified mice are not "products" of the animals with increased economic value; rather, they are generated in response to antigens introduced through genetic modification of the mice's genome.

The Court further supported its reasoning by referencing the Guidelines for Examination of Biotechnology Applications for Patents issued by the Indian Patent Office. These guidelines include examples analogous to the subject matter of the present invention, reinforcing its patentability.

Outcome

After a thorough examination of Section 3(i) and the relevant guidelines, the Madras High Court set aside the Patent Office's rejection order and directed that the patent application be allowed to proceed toward grant.

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