

## Legal Issue in 'Patenting & Technologies'

Issue: Whether a Species Claim is Disclosed in a Prior Genus Claim in a Markush Formula?

## Introduction

- ❖ Increased protection of a subject-matter in use through multiple interfaces between related product/process patents.
- ❖ An external factor to patent prosecution being research cycle of the patentee and its progress on multiple technologies that could be brought to the market.
  - Genus – the superset of claimed product; Species: a narrower subset of the genus.
- ❖ Inventive step requirement as one of the three facets of Patentability.
- 2 ❖ Unity of invention and inventive step requirement to prevent claiming the same invention through multiple patents.

## Relevant Provisions of the Patents Act, 1970

- ❖ **Section 2(1)(ja):** *"inventive step" means a feature of an invention that involves **technical advance** as compared to the existing knowledge or having **economic significance or both** and that makes the invention not obvious to a person skilled in the art.*
- ❖ **Section 2(1)(l):** *"new invention" means any invention or technology **which has not been anticipated by publication in any document** or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.*
- ❖ **Section 10(5):** *The claim or claims of a complete specification shall relate to **a single invention, or to a group of inventions linked so as to form a single inventive concept**, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification.*

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## Markush Claims

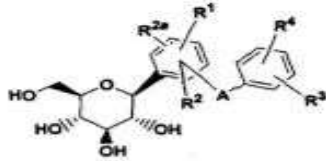
- ❖ Claims relating to a single inventive concept.
- ❖ A possibility to avoid disclosing each and every possible combination of a claimed product that would have the same or a similar effect/functionality.
- ❖ Different combinations as known to the person ordinarily skilled in the art (POSITA).
- ❖ Markush claims amounting to genus claims.
- ❖ Intended outcome of such claims being that individual species claims as well are protected.

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## Example of Markush Claim

What is Claimed:

1. A compound having the structure



wherein

$R^1$ ,  $R^2$  and  $R^{2a}$  are independently hydrogen, OH, OR<sup>5</sup>, alkyl, CF<sub>3</sub>, OCHF<sub>2</sub>, OCF<sub>3</sub>, SR<sup>5i</sup> or halogen, or two of  $R^1$ ,  $R^2$  and  $R^{2a}$  together with the carbons to which they are attached can form an annelated five, six or seven membered carbocycle or heterocycle which may contain 1 to 4 heteroatoms in the ring which are N, O, S, SO, and/or SO<sub>2</sub>;

$R^3$  and  $R^4$  are independently hydrogen, OH, OR<sup>5a</sup>, OAryl, OCH<sub>2</sub>Aryl, alkyl, cycloalkyl, CF<sub>3</sub>, -OCHF<sub>2</sub>, -OCF<sub>3</sub>, halogen, -CN, -CO<sub>2</sub>R<sup>5b</sup>, -CO<sub>2</sub>H, COR<sup>5b</sup>, -CH(OH)R<sup>5c</sup>, -CH(OR<sup>5b</sup>)R<sup>5d</sup>, -CONR<sup>5e</sup>, -NHCOR<sup>5c</sup>, -NHSO<sub>2</sub>R<sup>5d</sup>, -NHSO<sub>2</sub>Aryl, Aryl, -SR<sup>5e</sup>, -SOR<sup>5f</sup>, -SO<sub>2</sub>R<sup>5g</sup>, -SO<sub>2</sub>Aryl, or a five, six or seven membered heterocycle which may contain 1 to 4 heteroatoms in the ring which are N, O, S, SO, and/or SO<sub>2</sub>, or  $R^3$  and  $R^4$  together with the carbons to which they are attached form an annelated five, six or seven membered carbocycle or heterocycle which may contain 1 to 4 heteroatoms in the ring which are N, O, S, SO, and/or SO<sub>2</sub>;

$R^5$ ,  $R^{5a}$ ,  $R^{5b}$ ,  $R^{5c}$ ,  $R^{5d}$ ,  $R^{5e}$ ,  $R^{5f}$ ,  $R^{5g}$ ,  $R^{5h}$  and  $R^{5i}$  are independently alkyl;

$R^6$ ,  $R^{6a}$ ,  $R^{6b}$ ,  $R^{6c}$ , and  $R^{6d}$  are independently hydrogen, alkyl, aryl, alkylaryl or cycloalkyl, or  $R^6$  and  $R^{6a}$  together with the nitrogen to which they are attached form an annelated five, six or seven membered heterocycle

- ❖ (Partly) Claim 1 of Indian Patent No. 205147.
- ❖ The basic structure of the compound that could be used to treat type-II diabetes.
- ❖ Possible combinations of the structure with different groups run into millions of molecules.
- ❖ Boundaries of patent protection?

## Requirements of Patent Law & Markush Claims

- ❖ A species compound/product of a claimed genus may always be encountered by further research and its utility realised.
- ❖ Unity of invention as a barrier to avoiding protection to the same product under both genus and species patents – leading to an extended period of protection.
- ❖ Obviousness-type double patenting meant to invalidate the species patent.
- ❖ Does a patent still protect a compound when it has not been explicitly acknowledged but covered by virtue of a Markush claim?

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## Relevant Case Law

- ❖ The Supreme Court, in *Novartis AG v. Union of India*, (2013) 6 SCC 1, rejected the argument that there was a dichotomy between coverage and disclosure and ruled that all molecules covered by the genus patent in that case were/are known therefrom.
- ❖ Question on disclosure-coverage dichotomy was thus resolved.
- ❖ But the standard of determination and certainty of disclosure through Markush claims still remain unaddressed.

## POSITA as Reference & Fact-Dependence

❖ ***Astrazeneca AB & Anr. v. Intas Pharmaceuticals Ltd.*, [FAO (OS) (Comm.) 139/2020, decided on 20th July, 2021]**

- Explicitly undisclosed drug from a genus patent was disclosed in a species patent. Respondents-defendants alleged to have infringed the appellant's rights under both the patents.
- *“Conversely, once the appellants / plaintiffs claimed infringement of [the genus patent] also, it necessarily followed that DAPA was subject matter thereof and once it was the subject matter thereof, how it could be the subject matter of subsequent [species patent].”*
- 8 • *“even though none of the 80 compounds disclosed...have 'ethoxy', but Section 10(5) would have enabled the appellants/plaintiffs to claim that merely from substitution of 'ethoxy' for 'methoxy' disclosed in one of the 80 compounds, it could not be contended that there was no infringement, inasmuch as it was a part of the single inventive step, **subject matter of [the genus] and both 'ethoxy' and 'methoxy' being 'lower alkyls'.**”*



## Resolving to Avoid Double-Patenting

- ❖ Realization of utility of a covered species compound through further research does not cover the inventive step requirement for a second (extended) protection of the compound.
- ❖ The umbrella of single inventive concept wide enough for protecting such compound.
- ❖ Fact-dependence and standard of further protection deriving from a single Markush claim cannot be generalized by adverting to reductionism.

# THANK YOU!

## Questions?

**Ashok Vardhan Adipudi**, Trainee Associate

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