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Coverage-Disclosure Conundrum and Future of Species Patents in India

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"*Discovery consists in seeing what everyone else has seen and thinking what no one else has thought*."
Albert Szent-Gyorgyi (Physiology Nobel laureate)

Innovations are mostly derived from already existing technologies that may or may not have been patented. What could one think of, about the patentability of a product, let's say a pharma product that is made from the group of previously known compounds, some of which are already patented? The answer to this question lies in the very technical field under patent law known as 'Selection Patents' or 'Genus-Species Patents'. Predominantly this concept of selection patent or species patent is seen mostly in the domain of chemical compounds or species, but certainly is not limited to that only, as the same can be applied in other technological areas, such as engineering, biotechnology, material science and telecommunications.

Selection patents/inventions are said so as they overlap with the disclosures in the preexisting art. Such aforesaid disclosures generally do not hamper the novelty of the latter invention unless the latter one does not encompass a new embodiment of feature or property. But this isn't as straight forward as it seems to be. The critical issue in this domain is how to determine the novelty and inventive step of the selection inventions which are entangled in the dichotomy of coverage and disclosure. Off late there have been chunk of cases in India deciphering the coverage-disclosure conundrum in the field of species patents. This paper will foray as to what is this coverage-disclosure conundrum in selection patents, what are the legal framework that are prevalent across other jurisdictions to deal this and what is the future of specie patents in India especially in light of recently filed Dapagliflozin Appeals.

Keywords: Coverage-Disclosure, Genus-Species, Patents, Dapagliflozin, Markush claims, Self collision

Innovations are mostly derived from already existing technologies that may or may not have been patented.[1] What could one think of, about the patentability of a product, let's say a pharma product that is made from the group of previously known compounds, some of which are already patented! The answer to this question lies in one of the aspects/technical fields under patent law known as 'Selection Patents' or 'Genus-Species Patents'. Predominantly this concept of selection patent or species patent is seen mostly in the domain of chemical compounds or species, but certainly is not limited to that only, as the same can be applied in other technological areas, such as engineering, biotechnology, material science and telecommunications.[2]

The conditions for a valid selection patent across jurisdictions including India do not constitute an independent basis upon which to attack the validity of patent.[3]

Thus, technology and industry do appear to matter a lot when patents are challenged on disclosure and definiteness.[4] Selection patents/inventions are said so as they overlap with the disclosures in the pre-existing art. Such aforesaid disclosures generally do not hamper the novelty of the latter invention unless the latter one does not encompass anew embodiment of feature or property. But this isn't as straight forward as it seems to be. The critical issue in this domain is how to determine the novelty and inventive step of the selection inventions. Off late there have been chunk of cases in India deciphering the coverage-disclosure conundrum in the field of species patents.

There do exist guidelines and tests for accessing novelty of Selection Inventions in some jurisdictions e.g. in Europe by EPO, but in contrast there is nothing as such in guidelines issued by IPO.[5] The guidelines though permit the essence of selection inventions in pharma and allied subject matter, but they are silent about criteria to be adopted while granting patent to such inventions. Indian Judiciary on the other hand do recognize the patentability of such inventions as well but hitherto they too haven't demarcated the assessment of novelty & inventive step for determining the patentability of selection invention

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and instead rely on the principles laid down in the UK decision in *IG Farbenindustrie AG's Patent [(1930) 47 RPC 289]* for determining the inventive step in a selection invention. For instance, Bombay high court followed the same in *Farbwerke Hoechst and B. Corporation* v*Unichem Laboratories (AIR 1969 Bom 255).*

What motivated us as authors of this paper are some of the recent developments, along with recent decided case laws in the concerned field? The cases though got decided on the merits and the existing legal framework but have left some unanswered questions and plethora of futuristic debates in this very field of 'Genus-Species Patents', that we as a student of IP Laws would like to dwell upon. This research paper has tried to analyze as to what is this coverage-disclosure conundrum in selection patents, what are the legal framework that are prevalent across other jurisdictions to deal this and what is the future of species patents in India especially in light of recently filed Dapagliflozin Appeals.

From *Novartis*[6] to *AstraZeneca*[7]: Genesis and Evolution of Debate over Coverage and Disclosure

It was the case of Novartis in year 2013 that saw the beginning of debate as to what the dichotomy between 'Coverage' and 'Disclosure' can be under patenting framework.[6] Ever since then few other cases have given us jurisprudence to dwell upon this domain. Let us try to go through them to find out the prevailing scenarios.

The Supreme Court of India in Novartis case rejected the Appellant's argument that the scope of coverage is way much wider than what is disclosed in specification of the very patent application. The Court opined that there cannot be humongous gap between "disclosure" & "coverage" under a patent and, therefore, *via* smart drafting, a patentee cannot claim that the Genus patent has not disclosed the compound of the species patent even though the compound is covered by the Genus patent.[6] This decision almost equated both Coverage & Disclosure on same platform as one and same. This ratio decidendi has provided luminance to a grey area in examining "covered" & "disclosed" compounds and has paved the path to examine Genus-species patent applications on similar lines, but, of course, conclusions varied based on case-to-case basis.[8]

The dichotomy which exists between coverage i.e.claim on the one hand and that of disclosure i.e. enablement on other hand, is precisely the rationale behind law of patent. The very essence of the patent law is that an economic monopoly is granted to the inventor for a particular period at the end of which the invention is supposed to get into public domain that may get benefit from it at large. And hence it would negate the fundamental rules of the patent law if the claim that coverage in any patent is well beyond disclosure is accepted. The court even went on to suggest that the law of patents in India must not develop on the lines where there exists astronomical gap between the coverage and the disclosure aspects.[6]

In another case of *FMC Corporation*[9], plaintiff argued that the product in issue was one of the substances covered by the Markush Claim of the very Genus Patent, but it is not possible for a person skilled in the art to synthesize the same without imagination and creativity. The defendant relied on the Supreme Court's verdict in Novartis case dealing with coverage & disclosure. The Delhi High Court noted that though the Markush claims cover the product in question, however, a detailed scrutiny of the Genus patent does not teach the product claimed in species Patent.[8]

The most contemporary judgment of the Delhi High court in this domain came in 2021 in case of AstraZeneca.[7] The question that came up in this case was whether the substance in issue i.e. Dapagliflozin (a drug to treat diabetes mellitus) was covered and disclosed in first patent (i.e. a genus patent covering group of substances which discloses the possibility of various permutation and combinations giving several other structurally diverse substances) rendering the fate of second patent (i.e. a Species patent covering Dapagliflozin exclusively) open to question along with other legal issues between the parties.

The claim of the plaintiff/appellant and the resultant reasoning by the Hon'ble Court was of significance concern for better understanding of the play-off between 'Coverage' and 'Disclosure'. The plaintiff/appellant in their claims inter alia suggested that (1) a substance/compound doesn't become disclosed with specificity by just being within the scope/periphery of a particular type of claim. (2) The aforesaid first patent is a 'Markush structure' (i.e. a patent encompassing a collection of substances, which can result from individual permutations and combinations making several million structurally diverse substances) and hence being so it, covered DAPA, though it obviously did not disclose the same.

The Court opined that there cannot be two patents for the same invention. And the various provisions of the Indian patent Act substantiate this understanding.

When we go through the definition of the 'Inventive Step' under the Patent Act, it clearly tells that invention in question must involve advancement on technical front compared to existing knowledge. Also, Clause (d) to Section 3 suggests that "*the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not an invention*". Hence for the aforesaid substance to get patented it must have fulfilled the following essentials.(1) it was to be a new product (2) it was to be a technically advanced product *vis-à-vis* existing knowledge if any (3) it was to have a utility for industrial application (4) it must not be obvious to a person skilled in the same field (5) the same must not have been published in any document (6) must not be in prior use before filing patent application. The Court after going through the complete specification of both the patents applied all these parameters to conclude that there was a complete identity between the subject matter of both the patents. Also as far as appellant claim of the concerned substance being covered in first patent but not disclosed in it was concerned, the Court very clearly told that the suit filed by appellant for infringement of the first patent itself shows the admission of the fact that the substance in issue is the same invention and subject matter in both the patents and without being disclosed in one claimed patent there could be no patent with respect to it. So, wouldn't it be incongruous on the part of plaintiff/appellant to claim an infringement action for a patent and still claim it to be not disclosed? So, in a way court suggested in its wisdom that Indian patent law so far do not discriminate between coverage and disclosure per se and hence the claim covering that aspect do not hold any ground.

As far as appellant's claim of the concerned compound to be a Markush structureand the same being a well-recognized concept under Indian patent law *vis-à-vis* Section 10 (5) of the Indian Patents Act, is concerned, Section 10 (5) provides that "*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*". Hon'ble Court analyzed that, when this provision is read along with other assorted provisions of the legislation, it only goes to prove that once the patent is granted with respect to one product the same is complete and is disclosed to world at large. Section 10(5) permitted the appellants/plaintiffs to obtain patent for group of inventions though forming only one inventive step. The same section also empowers the patent holder to sue for infringement if any product is made by doing slight variations in that aforesaid group of inventions. But facts of the case clearly indicates that first patent was merely a discovery of a scientific principle, and being so the same is barred by provisions of section 3 to be granted patent. But beyond shadow of doubt if the first patent did not disclose the substance in issue, there could not be any infringement at all.

Hence the Court made it amply clear that Indian patent act do not recognize patentability of any important stage from a larger inventive process if the same is not capable of any utility in the industrial application even if it encompasses a technical advancement *vis-à-vis* the existing knowledge.[10]

One of the curious aspects of the DAPA case was that both genus and species patents were asserted. Patentees generally assert only the species patent. But this tendency of the patentees to assert patents as per choice was dangerous if courts were to distinguish cases based on how many or which patents are asserted.

FMC case is distinguished from the DAPA case since in FMC only species patent was asserted but if this is made the matrix for distinguishing cases then learning the lesson from DAPA, no patentee would be unwise to assert both genus and species patents. Such a trend will ultimately dilute the DAPA DB order.

International Scenarios

The most basic tenet of law is that it can never be studied in isolation. And for a subject as technical as this it would be better to take a glimpse across various other jurisdictions as to what is the situation prevalent there.

When we step in the USA, our area of study touches a concept there, known as 'Second generation' i.e. a drug products which is way beyond the big brand drug product and they are developed to give improved efficacy, ease and safety to its users. The resultant patent of those underlying second generation drugs provides an intangible worth to the pharma companies who innovate those second gen drug in quite a shadow to gain successive layers of the patent protection to their already existing products. But in order to be worth patenting that aforesaid second-generation drug must be worthy of some

effective economic gain as is ensured by the Patenting Framework of USA (and increasingly by the patenting framework elsewhere). In essence such economic capitalization or gain *vis-à-vis* that second-generation drug to give more life or protection to the already existing depends on the national patenting framework along with regulatory mechanism for the same. Though, the authors are aware that the US Patent Law does not have Section 3(d) & Section 53(4). Another hurdle which these second-generation patents are prone to is the claim that subsequent invention under second generation product is not distinct from the already existing one i.e. those claimed under first generation, and hence those second generation ones renders themselves invalid under the doctrine called as "obviousness-type double patenting".

The present framework under US Patent Law provides that validity of a claim depends on whether it was 'enabled' (in its strict legal sense) that too across its full range or not.This provision is equally applicable to Markush claims as to other claims. However, whether the inventor has in reality processed and synthesized each molecule under the ambit of claim is not required per se under the US Law. So long as the inventor has provided with sufficient disclosure that would enable one of person skilled in the art to make and use the full scope of invention without indulging in undue instrumentation, it is quite possible for a claim to be enabled even though it covers millions of compounds, the vast majority of which have never ever been synthesized.[11] There are also a set of guidelines that assort these legal provisions by maintaining that "*coverage of the patent should be limited to the claimed embodiments that are actually enabled by the disclosure in the specification*".[12] This in turn implies that the US framework along with guidelines would consider the Markush type claims for the patentability if all the ingredients that are covered by the claim are in fact "actually enabled".

When we shift our analysis to Europe the concept of Genus-Species patent encompasses a concept called as 'Self Collision'. This Self-collision comes aboard when an applicant files an application under European patent which corresponds to subject matter of any priority document (i.e. to say a species claim) and another one which broadens that very subject matter (i.e. to say a genus claim).[13] In these cases of self-collision, it's the species claim only that gets all the dividends from the very priority right itself, and as far as genus claim is concerned it retains the actual date of filing. So, this confrontation creates a situation of faceoff between these two applications as the species claim becomes part of the prior art relevant for the examination of the genus claim, destroying its novelty.[13]

The European patenting framework also provides for a framework to resolve this confrontation called as self-collision by means of following two methods (1) giving a general disclaimer in the very genus claim itself / (2) a concept called as 'Doctrine of Partial Priority'. This doctrine suggests that the subject matter of the species i.e. within the ambit of genus claim and which corresponds to the species claim which is already filed, would get entitled to its priority date. So, with this doctrine in place along with broader interpretation of few legislative provisions e.g. Article 88 EPC (European Patent Convention, this issue of self-collision along with resultant risk of double patenting can be dealt with much ease.

Some European jurists have suggested a possible way out from this risk of double patenting by allowing only those genus claims, which covers howsoever implicitly the subject matter of species which is earlier filed, for the entitlement of date of partial priority of that very species, if and only if the subject matter of the species and the residuary subject matter which is not overlapping are unambiguously and directly disclosed in the application of genus patent itself.

European patent law also entails the concept of 'Purposive Selection', which makes a selection invention invalid if it is an arbitrary specimen from an existing art. Recently the High court of Delhi applied the same principle to declare the invention in issue as inventive and novel.[14]

The position in England is bit different from that of corresponding UK. In light of I.G. Farbenindustrie's Patent (1930), The High Court of UK has held that a selection patent won't be held valid until it is met with following conditions *vis* '(i) a selection patent in question must be based on some of the substantial advantage from the use of selected members; (ii) the whole of selected members must be in possession of the advantage in question; (iii) the selection must be with respect to quality of a special characterthat is peculiar to a selected group'.[15]

J Floyd of the UK High Court went on to suggest that the concerned legislation does not encroach

upon any provisions of the EPO case laws and the coherence position between the two can be summarized as:

(i) The novelty of any specific claim with respect to any specific substance is not rendered unworthy because of mere prior disclosure of the same unless the very substance is disclosed in isolated form.

(ii) Patent applicants often use a general disclosure for their invention which latently covers a humongousnumber of chemical substances, and which obviously does not necessarily abrogate the novelty of any further specific substance e.g. a general disclosure of 'fixing means' won't necessarily discloses a nail.

(iii) If multiple substituents which are chosen from a list makes a general formula, then in normal course of routine it will not render the novelty of any subsequent claim for any isolated substance as invalid.

(iv) It still remains dubious *vis-à-vis* EPO jurisprudence if any newly discovered outcome would be suffice enough in overcoming a rather new finding about a substance that is specifically disclosed.

(v) Irrespective of novelty of any invention, the obviousness must be decided on the ordinary principles.

(vi) If any selected substance encompasses any new advantage over the existing knowledge then it is necessary but not sufficient in the verification of the obviousness.

(vii) Non-compliance *vis-à-vis* the provisions of IG Farbenindustrie's *per se* won't render the fate of inventive step.

(viii) As far as Markush claims are concerned, it would be unreasonable to believe for any prudent man that all the possible millions of structures of any formula can be jotted down by any person skilled in that very art and hence any earlier document does not contain any clear description regarding how to do something or not to do something to infringe the claim of patentee.

A decided case law from Chinamight give more insight into the functioning of Markush claims and its interface with the municipal legislations. Supreme People's Court in December 2017 gave a decision on a case concerning Chinese patent in which the court gave a comprehensive reasoning concerning Markush claims that such claims are often generalized by explaining alternative substances in a parallel in any single claim, and the reason such drafting ways looks so is that, for certain substituents in the chemistry there exist no generic term which is quite common. Such drafting ways are never considered as functional but are always considered as structural expression per se. The Markush claims define alternative substances in parallel but not the sub claims. Also being highly specialized the Markush claims once after getting protection shall cover almost all the substances having common properties, structure etc. giving the maximum benefit to the patentee. Thus, if seen from the perspective of justice the analysis of Markush claim must be done strictly, irrespective of howsoever permutations and combinations any such claim comprises it must be deemed as a solution comprising of generalized solutions. In view of the above the Markush claim shall be deemed as a collection of Markush elements rather than a collection of individual compounds.[5] So generally speaking, the Markush substances shall mean to represent one genre of substances sharing common attributes and outcomes, and it can represent to mean a single substance only in clear specified circumstances.

The afore discussed case law of British pharma giant AstraZeneca where it found itself stuck in a complicatedly knit legal web, also came to conclusion last month, where the aggrieved company pleaded before the Hon'ble Supreme Court claiming the same reliefas it pleaded before Delhi High Court for restraining someIndian pharma companies from selling theDAPA's substitutesin the markets at a lower price brackets coupled with allegation that the decisions by the different benches of DHC on the appeals were apparently contradictory and thereby are a source of confusion and uncertainty for both AstraZeneca and the other companies reselling the generic substitutes of the compound. The company also proposed that the said drug was completely man-made and research based invention and the same cannot be found in nature. However the Supreme court rejected the pleas of the company and also reprimanded it along with imposition of a fine for trying their luck with every bench that they could approach.

Way Forward

The requirement of Disclosure forms the very core of patent law. Across almost all the jurisdictions,

patent without full disclosure renders the invention invalid and hence to get an authentic and sustainable patent disclosure is a sine qua non. So having discussed the global scenarios and the hitherto situations in India, let us see as to what can be done.

Amongst various global jurisdictions it can be clearly seen that patentability in pharma industry is quite intriguing a concept because of existence of what is called as 'Markush claims' i.e. an application of patent covering 'X' number of substances, which are often came to known as "Genus application", while another relative subsequent concept is that of ''Species application'', in which an application for patent have specific substances that may have been already covered in the Markush claims of the aforesaid genus patent. We can say that these Genus-Species patents share relation of parent and child in which genus patent inculcates a broader coverage of the invention while the Species patent inculcates a specific coverage. The main issue that is faced in examining the patentability of such Species invention is what substances are 'covered' (that is to say covering a substance which has not been specifically exemplified in any form of the embodiments of specification)[8] in the genus patent application and which of them are 'disclosed' (that is whichdenotes a particular group of substance(s) either given as is in any of the embodiments of the specification or has been exemplified explicitly[8]) in the same and hence is the conundrum between the 'coverage and disclosure' of the substance in issue.

We also came to see that hitherto there exists no legal provisions in the patent act which deals explicitly with these kinds of patents, and they are dealt in the same framework as is applicable on other inventions e.g. Section 3&4. However, we can trace some provisions dealing with coverage disclosure conundrum in some other regulations and also from judicial precedents for example:

(i) Guidelines for patenting in pharma products[16] in pointer 7.2, discloses the provision regarding assessing novelty of the Marksuh type of claims. It propounds that any generic disclosure does not necessarily abrogates the novelty of any specific disclosure. Hence, while assessing novelty of the application concerning species patent over application of Genus patent, determining whether that species is explicitly disclosed in the Genus Patent and if such disclosure is of enabling nature, would be imperative. The Guidelines further states that if any disclosure is so much so implicit in any of the prior art such that it creates a doubt in examiner's mind, an objection on novelty can be imposed. Further, in maximum instances, disclosure of a prior Genus application which is implicit might not be prejudicial as far as novelty of invention is concerned, however, it can still be amotivating disclosure and its inventive step may be examined (for the application for Species Patent).[8]

(ii) Another criterion which came from certain precedents is that straw-picking of substituents from the documents of multiple prior art, without showing what would motivate the person who is skilled in the art to straw pick, is not permissible in analysis of inventive step or obviousness.[17] *(Merck Sharp and Dohme Corporation* v *Glenmark Pharmaceuticals, 2015 (64) PTC 417 (DEL); Bristol-Myers Squibb* v *BDR Pharmaceuticals International Pvt. Ltd., CS (COMM) 27/2020 (MANU/DE/0299/2020); FMC Corporation & ANR* v*Natco Pharma Limited., CS (COMM) 69/2021*).[8]

As far as conflicts with respect to this selection or genus-species patents are concerned, it is observed that it is the genus patent holder that usually files the infringement suit. So before concluding this discourse we will also try to understand as to what are the practical aspects that this conundrum faces.When one visits the deep aisles of pharma industry one often finds that research and development in industry as complex as pharma is indefinite and hence after filing an application for genus patent for a particular substance, the research still continues to find a more efficacious substance over and above what is already been patented, often keeping it as base for the subsequent development. As a result of such add on development subsequent specific substances which shows advantage that is unexpected and is far more effective vis-à-vissubstances in the same family, which is covered in Genus application, are found, thus, protecting the said substance in any new patent application which are often called as application for species patent.[8]

It wouldn't really be an exaggeration in suggesting that aforesaid subsequent species invention might not be quite feasible had it not got a base of the genus invention. Also, one would definitely agree that continuing research from already existing base takes

less time, efforts and capital then starting from scratch. Hence the species inventions and resultant patents usually belong to the owner of genus invention itself. And to suggest that such genus Specie relationship gives rise to evergreening of patent resulting into monopoly in the pharma market might not be fully wrong.

As far as future aspect of this very domain is concerned the developing stage of India as an economy has much to do with this. Our political structure based on socio economic model of planning ensures ripening of dividends by the one who sow the seeds and simultaneously ensuring the equal sharing of dividends among the society as a whole for an inclusive growth. As of now the entire patenting framework in nearly all the jurisdictions across the globe is unclear and is ever evolving with respect to the operation of species patent, leaving the entire fate of it on the wisdom of judiciary leading to varied interpretations with some agreeing to it while others not. A mirrored situation is also in existence in India coupled with another hurdle of comparatively naïve jurisprudence of IP Laws leading to varied interpretations. *Inter alia*, a judgment worth mentioning is of the division bench of Delhi High Court, the ratio decidendi of which suggests 'one product, one patent'. And we would leave this on the discretion of readers to decipher the direction in which said issue is heading. Certainly, there may arise need in near future to either include or exclude this issue of specie patent explicitly along with well framed criteria and rules regarding its functioning either *via* legislation or probably by the Highest Court of the country to overcome the varied dictums that are prevalent hitherto. And in the capacity of subjects of a welfare state we understand that everyone would agree that species patents if given a green flag would certainly inculcate a pro patent approach, paving another way for India to be on the path of developed nations. In this regard it might be interesting to note the provision of Section 53(4) of the Patents Act wherein "*on expiry of the term of the patent, the subject matter covered by the said patent shall not be entitled to any protection*". This provision might become critical to ascertain if there are compounds covered under a genus patent then can the same also be patented again via a specie patent only because the complete disclosure occurs in the latter patent. Will it then be wise to grant genus patents which are nothing more than theoretical or conceptual inventions without any direct industrial applicability simply on basis of borrowed practices from US and European law which are jurisdictions with very different socio-economic and constitutional ethos as well as considerable differences in the basic criterion of patent laws. Perhaps a determination by the Superior courts or the legislature will be critical to ensure affordable access to medicines in India and thwart multiple patents on same or undeserving innovations.

Now after seeing that coverage and disclosure conundrum gave birth to none less than infringement suits, we can conclude our discourse by mentioning that as there exists no well framed guidelines from the office of Indian Patent or anything under Patents Act and Rules, regarding interpretation of terms "coverage" and "disclosure", and whatsoever is there is quite naïve and varied so until there comes a well guided framework, we must rely on thejudicial wisdom in this domain to determine the validity of any such selection/ genus-specie patent as this novel concept have become a very complex factor in determining the success in any infringement suits of any patent.

References

1 Ahn H, Patentability of chemical selection inventions: The Olanzapine and Escitalopram decisions, *Nomos Verlagsgesellschaft*, 2011, 11.

2 https://www.mondaq.com/india/patent/719486/selection-patents-a-developing-area-of-indian-patent-law(accessed on 3 February 2022).

3 Hakert J D, A hard pill to swallow: A critical look at Eli Lilly & Co.'s NAFTA challenge of the Canadian Patent Regime, and its potential side effects, *The International Lawyer*, 47 (2013) 520.

4 Allison J R & Ouellette L L, How courts adjudicate patent definiteness and disclosure, *Duke Law Journal*, 65 (2016) 669.

5 https://www.mondaq.com/china/patent/750560/interpretation-of-markush-claims-in-a-recent-supreme-people39s-court-decision (accessed on 18 March 2022).

6 *Novartis AG* v *Union of India*, (2013) 6 SCC 1.

7 *Astrazeneca Ab &anr* v*Intas Pharmaceuticals Limited &ors*, (2021).

8 https://www.mondaq.com/india/patent/1117710/genus-species-patents-patentability-in-india (accessed on 10 February 2022).

9 *FMC Corporation & ANR* v *Natco Pharma Limited.* (CS (COMM) 69/2021).

10 What exactly is the industrial applicability of a Markush? Why do we grant Markush or genus patents if they are mere research tools with no real-world applicability? -this is where the Carlos Correa's distinction between utility and industrial applicability comes into play- Markush might sit well in US jurisprudence since utility is broad to cover inventions which are research tools- but can we use Markush in an industry? No because it is just a structural concept- a conceptual invention where substitution is required but if a court kills

the concept of Markush today it will disrupt years of practice in patent office of granting Markush patents in India.

11 Holman C M, In defense of secondary pharmaceutical patents: A response to the UN's guidelines for pharmaceutical patent examination, *ILI Law Review*, 50 (2017) 761.

12 Veldsquez G, *Guidelines on Patentability and Access to Medicines (S.* Ctr. Working Paper No. 61, 2015)(citing commentary from parties such as the Minister of Health of Argentina, Secretary-General of Thailand's Food and Drug Administration, and the Minister of Health of Brazil, expressing gratitude, appreciation, and congratulations to the WHO for drafting and publication of the Guidelines).

13 Butriy O, 'Self-collision' of European patent applications under the European Patent Convention: What about partial priority? *Journal of Intellectual Property Laws & Practice*, 11 (2016) 682.

14 *Sulphur Mills Ltd.* v*Dharmaj Crop Guard Ltd. &Anr.* [CS (COMM) 1225/2018, 2 August 2021].

15 Wyld O, High Court considers Markush claims and the doctrine of UK selection patents, *Journal of Intellectual Property Laws & Practice*, 4 (2009)148.

16 The Guidelines for Examination of Patent Applications in the field of Pharmaceuticals, October 2014. The guidelines are not law- and that any change in interpretation by court or change in law by legislature will require the guidelines to be amended.

17 This is from an infringement point of view, for the patentability point of view an inventor can pick from a mosaic and show that it is inventive since Person Skilled in the Art couldn't do it, but inventor can.