

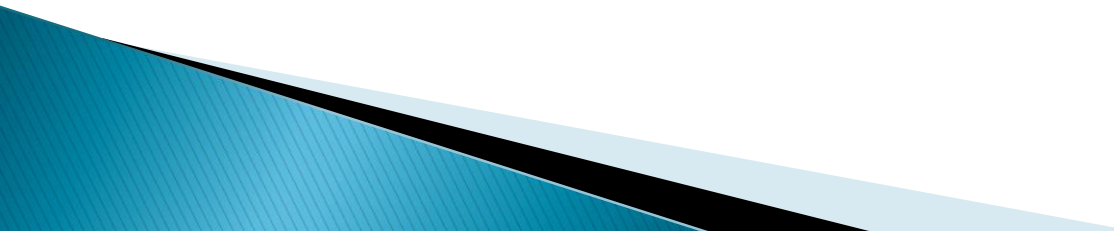
COMMENTS RECEIVED
ON
DRAFT GUIDELINES FOR EXAMINATION
OF PATENT APPLICATIONS IN THE FIELD
OF PHARMACEUTICALS

Issues on General Matters

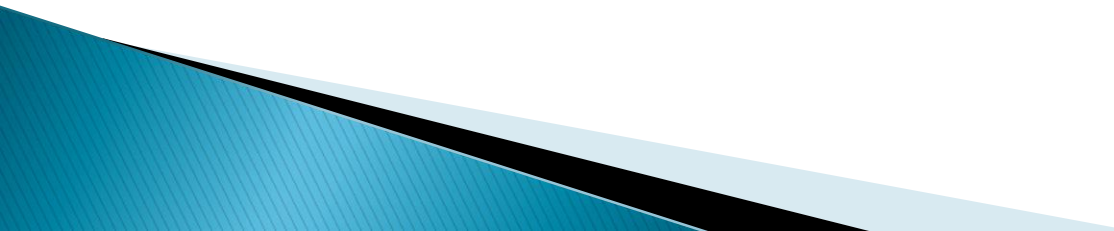
- Differentiating “good” and “bad” patents creates biases
 - Distinctions between pharmaceutical and other patents is unwarranted and inconsistent with TRIPS
 - Guidelines are to be made by all stakeholders of the Patent system
 - Reference of Ordinance regarding mailbox applications not mentioned
 - Clarity required wrt requirement of disclosure of source & geographic origin of biological material
 - Linkage established between the Patents Act & the Biological Diversity Act
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Issues on General Matters

Illustrative examples

- Illustrative examples give wrong interpretation & hence disclaimer to their non-limiting nature to be added
 - Balanced approach of positive & negative examples is required
 - References of reported decisions to be identified and illustrations to be based on judicially decided cases
 - Criteria for selecting prior art documents to be provided
 - Examples for pro-drugs & metabolites no given
 - Unity of invention and Section 16 to be linked
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Issues on the Scope & Provisions Covered

- To indicate that the guidelines would be updated periodically
 - Provisions of Section 2(1)(ja), Section 2(1) (ac) and Section 3(j) to be covered
 - Provisions of Sections & subsections to be reproduced
 - Provisions Sections 57 to 59 to be covered
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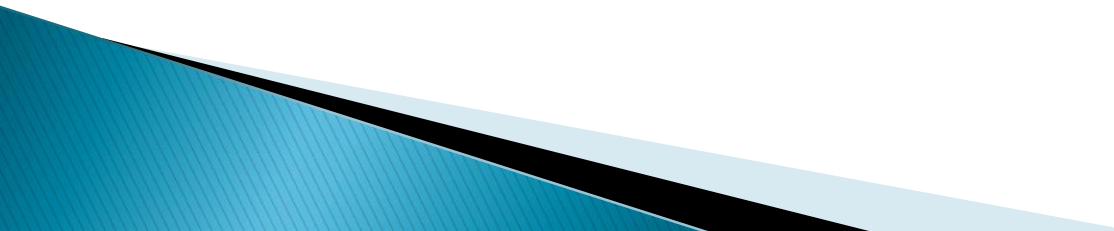
Issues on Claims of Pharmaceutical Inventions

- Term 'Pharmaceutical Substances' is inconsistent with its definition in the Act under Section 2(1)(ta)
- Standard term in industry, 'Active Pharmaceutical Ingredient', to be used instead of 'Active Ingredient'
- Use of certain inventions in a catch-all phrases to be avoided
- Text box on Markush claims creates unnecessary bias & requirement of “test conducted for each embodiment” is not as per the statute
- Statement related to the process of the text box on Markush to be reconsidered
- Requiring INN disclosure is burdensome and additional liability which is beyond the mandate of law

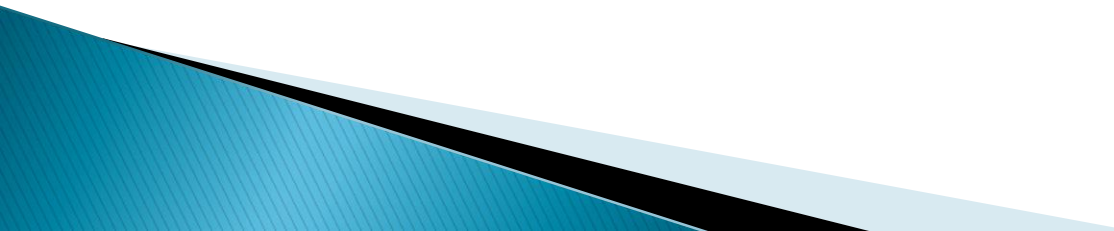
Issues related to Assessment of Novelty

- Use claims to be construed as process or even product claim and Swiss type claims to be allowed after amendment supported by the description
 - Clarification as to anticipation by prior use to be given
 - Term “combination of prior arts” is misleading wrt novelty
 - Distinction as to anticipation by Prior publication & prior claiming to be made & prior claiming to be cited against novelty only
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Issues related to Assessment of Novelty

- Implicit disclosure to be an issue of inventive step and not novelty & doctrine of implicit disclosure does not fit for definition of new invention
 - Inherent anticipation and implicit disclosure concern the same issue
 - Implicit disclosure is the one that a standard artisan can derive directly from the disclosure based on common technical knowledge
 - Examples in paragraph 7.6 to be revised so as to clarify “selection” inventions
 - No implicit disclosure in Paragraph 7.6 – Illustrative Example 2
 - Why the differences are not distinguishing is not clear from explanation and rationales wrt para 7.8 – Illustrative Example 2
 - In Paragraph 7.6 – Illustrative Example 3, no indication that the claimed compound is a necessary consequence of the prior art disclosure
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Issues related to Assessment of Novelty

- ▶ Product-by-process would be better discussed if three different possibilities, i.e. product is novel, process is novel and both product and process are novel
 - ▶ Example of product-by-process claim is inappropriate and misplaced
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Issues related to Assessment of Inventive Step

- The expression “existing knowledge” needs rewording and definition of prior art may be completed by a clarifying reference of prior rights (unpublished Indian applications) and the public nature of prior uses
- In Paragraph 8.5, the phrase “negative existence of novelty” cannot be extended to interpret question of novelty
- In the same para, the expressions "novelty" & "inventive step" as an alternative by using expression "or" is inappropriate, as it addresses inventive step and not novelty
- Different levels of a skilled person for obviousness versus enablement/sufficient disclosure is inconsistent with other jurisdictions
- The “person skilled in the art” may be a multi-disciplinary team rather than a single individual

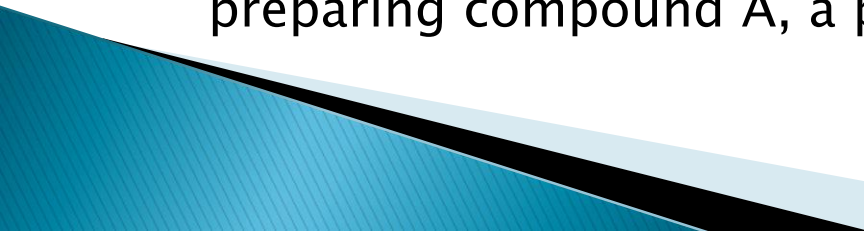
Issues related to Assessment of Inventive Step

- It is to be clarified wrt motivation to combine prior art that there must be some reason to lead the skilled person for selecting particular starting point and for making specific modifications required to reach the claimed invention
- The statement “In other words enhanced effects cannot be adduced as evidence of inventive step if they emerge from obvious tests” is opposed
- In Para 8.9, Method for objectively analysing inventive step lacks consideration of the global standards
- Para 8.10, Example 3 seems to be incorrect, as D3 would definitely dissuade the skilled person by the fact that besylate is used for 0.25% of the approved drugs

Issues related to Assessment of Inventive Step

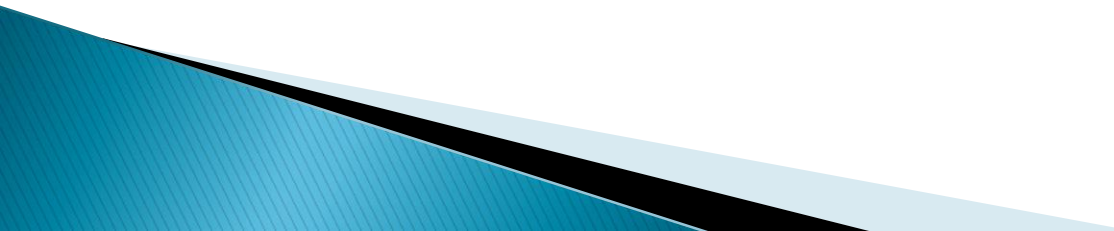
- It to be clarified that “obvious to try” does not mean varying all parameters or trying numerous possible choices until one possibly arrives at a successful result, where the prior provides no direction as to which of many possible choices provides a reasonable expectation of success
- Unexpected advantages over the compound(s) disclosed in the prior art to be considered on a case by case basis in assessing inventive step of such a novel salt
- Example based on IPAB decision of PEG Interferon dated November 2, 2012 has been stayed and therefore be removed from the guidelines
- Conclusion derived in illustrative Example 6 (that is based on the decision of IPAB in Pegasys case) does not seem to involve nuanced analysis according to the method recited on page 18
- In Example 7, there is no case law/document/explanation provided to adjudge whether the Micronisation for poorly soluble Drug D2 would have provided a reasonable expectation of success for a person skill in the art, to apply it to the claimed invention for improved drug delivery

Issues related to Industrial Applicability

- The word "Industry" to be understood in its broadest sense
 - The stipulation that "a concrete benefit" must be derivable "directly"..... from the description coupled with common general knowledge is not prescribed by statute
 - When embodiments of Markush claim not enabled or their utility has not been specifically disclosed, such 'paper compounds' not to be allowed
 - Illustrative examples are not clear, no case law provided to adjudge whether the use is "merely speculative", and the Act only requires to have an "industrial application" and doesn't require commercial viability
 - Illustrative example 2 is misleading, compound B is novel intermediate and it is unfair to deny to protect the novel intermediate disclosed to the public and it is crucial for preparing compound A, a pharmaceutically active compound
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Issues related to Inventions not Patentable

Issues of Section 3(b)

- Inventions contrary to morality to be clarified
 - Patenting of stem cells & other modified cells useful for therapeutic purposes to be allowed
 - There should be separate national agency/authority for assessing & deciding on safety matters & banning technologies that have adverse environmental impact
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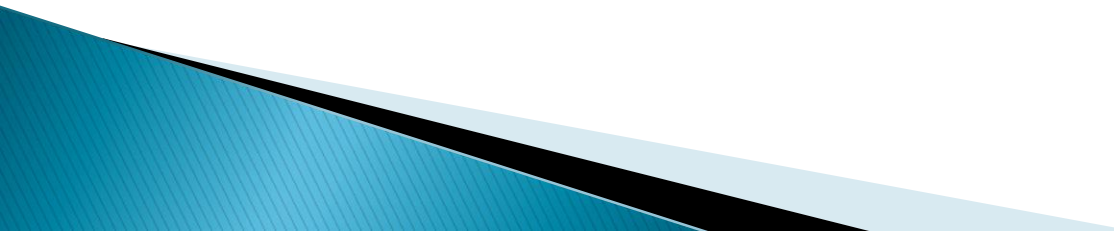
Issues of Section 3(c)

- Statutory limitations on Section 3(c) has been ignored as it only excludes discovery of living/non-living thing/substance and the entire sub-clause is qualified by the word 'mere'
 - Medicaments containing non-living substance occurring in nature for an altogether new use to be patentable
 - Applying the Biotech Guidelines to Pharmaceutical inventions is not appropriate
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Issues of Section 3(d)

- Amended Section 3(d) sets up a second tier for qualifying chemical substances/pharmaceutical products to be patentable & also sets an additional patentability criterion, which violates TRIPS
- No explanation on therapeutic efficacy has been provided
- “Mere discovery” is not clarified
- Efficacy should be “therapeutic efficacy” as per Novartis Judgment
- Examples do not cover all the aspects of Section 3 (d)

Issues on Section 3 (e)

- Clarity on the requirements of demonstrating synergy is to be given
 - More examples where more than one active ingredients are involved to be provided
 - Format of “kit” claims to be clarified
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Issues on Section 3 (i)

- Exclusion appears on face of Section 3 (i) is broader than the exceptions to patentability under TRIPS
- *In-vitro* diagnosis & treatment must not be read under the provision
- Method of diagnosis *per se* is not excluded from patentability because it doesn't amount to 'treatment' and requires medical care that cures certain condition/illness/ injury
- Cosmetic treatments are not the same as surgical methods and do not form part of the prohibitions under Section 3 (i) and the terms "cosmetics" & "purely cosmetic purposes" require explanation

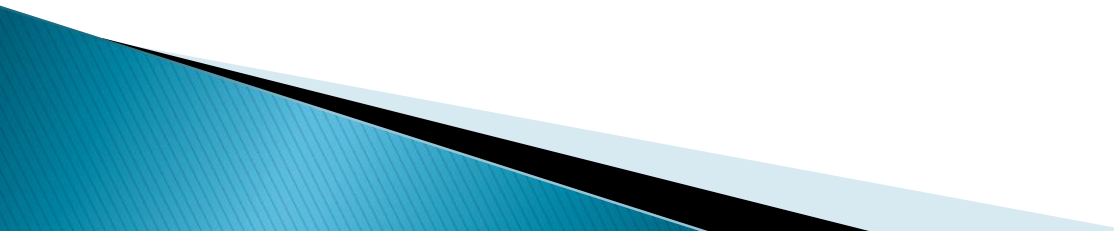
Issues on Section 3 (j)

- Isolated pure culture to be patentable since it is not available in nature as such & the term "genetically" modified is restrictive for patenting of microorganisms
- Exception to the provisions of Section 3(j) is genetically modified microorganisms & hence, the same should be applicable in respect of animals as well

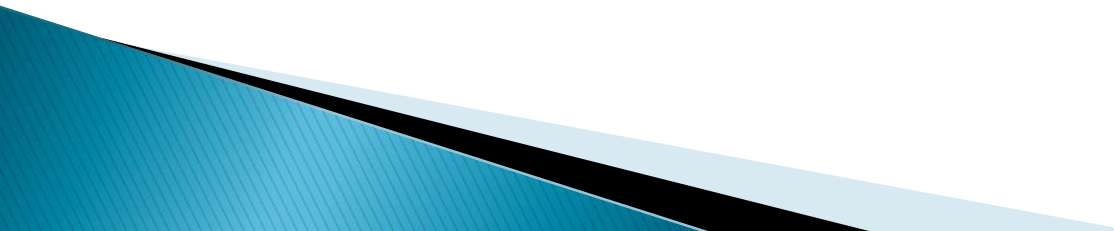
Issues on Section 3(p)

- The guidelines determined the scope of Section 3 (p) way beyond its de facto scope and implication and thereby proving to be detrimental to the Applicants, especially as regards the Guiding Principle 3

Issues on Sufficiency of Description, Clarity & Support of Claims

- Requiring deposit of material as a default rule when material has been fully described in the specification is contrary to the statutory mandate as well as the draft guidelines itself
 - Para 11.3 contradicts Para 11.2 and is contrary to the Act
 - Mandatory disclosure of source & geographical origin in each and every case is clearly not mandated in the law
 - Such requirements pose unacceptable risks for patent applicants and undermine the incentives of the patent system to promote research and innovation
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Issues on Sufficiency of Description, Clarity & Support of Claims

- Generalization of subject-matter in a claim with respect to the embodiments of the description should not be *per se* excluded & if novelty is acknowledged, the subject-matter could be regarded to cover "things" to be identified in the future in line with the invention
 - The "best method" requirement in Para 11.5 is being mixed with the requirement of enabling disclosure, both of which are quite distinct
 - Term "best" to be deleted from **line 3 of Para 11.5** & it must be ensured that the best method for performing the invention is too strict with a patent applicant in countries including India
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Issues on sufficiency of description, clarity & support of claims

- For establishing enhancement of therapeutic efficacy, external evidence may suffice as the Hon'ble Supreme Court relied on external evidence i.e. expert affidavits in the Novartis case
- Term “all” in line 3 from the bottom of Para 11.6 to be replaced with “at least one”
- Distinction between “enablement man” & “obviousness man” cannot be applied during examination as skilled person in the context of enablement has been given only in Section 64, which is related to Revocation of Patents
- Affidavits by non-Indian persons wrt enablement of the disclosure should not be relied upon for ascertaining enablement & workability since enablement is tested wrt a person in India having average skill & average knowledge [Section 64(1)(h)]

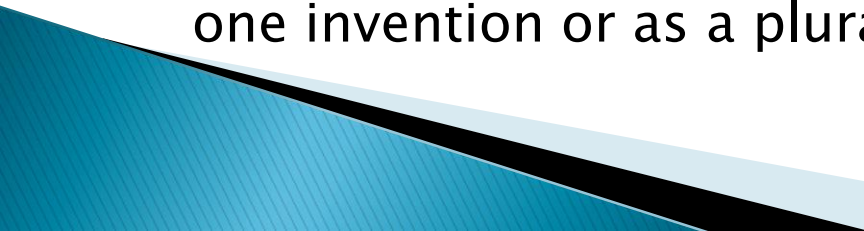
Issues on Sufficiency of Description, Clarity & Support of Claims

- Guidelines is silent about the situation where the disclosure of invention is complete, but additional data is required in order to meet requirements of objections under Section 3(e) & 3(d)
- Wrt Para 11.8, it should not be taken to preclude the consideration of information submitted after the filing date which confirms a relevant technical contribution if the relevant invention had originally been sufficiently disclosed in a verifiable manner
- Wrt “Test conducted and data provided can be predictive in humans and should be accepted by the skilled person”, it is not clear if it is required that in vitro/in vivo animal models data should necessarily be predictors of the biological effects in humans

Issues on Sufficiency of Description, Clarity & Support of Claims

- Wrt “11.12..... Claims may embrace non definitive terms like “comprising”, “including”,...”

Statement to be revisited as the transitional phrases “comprising”, “consisting of”, etc, apparently define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim as there is no statutory provision in the Indian Act for “doctrine of equivalents” such strict language of granted claims would provide an easy escape route for unscrupulous third parties

- Para 11.13 on functional claims to be clarified
 - Section 11.14 does not provide a workable standard to evaluate whether a Markush grouping is to be considered as one invention or as a plurality of distinct inventions
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Issues on sufficiency of description, clarity & support of claims

- Illustration 11.17 defeats the very purpose of having “Markush type claims” as substitution of the non-essential or inert substituents will yield a molecule that will be functionally no different than the exemplified representative compound
- The ambit of claims is not restricted to the disclosed examples & requirement of enablement is met when the disclosure is such that enablement person should be able to derive the claimed invention by varying the Markush definition
- In Illustration 11.17 (Example 3) separate example with G1 = sulphur may be justified only if the substituent is an essential substituent, that impacts the core functional activity of the representative compound

Issues on Unity of Invention

- It would be helpful to include guidance on the procedure for curing objections based on Unity of Invention, such as the use of limiting amendments & filing of divisional applications based on earlier priority applications
 - In Para 12.2, "is not desirable" is unclear– is this allowed or not?
 - Assessment of unity without explicit representation of structure(s) of formula (I), formula (A) and formula (X) is misleading
 - In Illustrative example for Unity of invention in Intermediate and Final Product example 1 the said the structural representation are missing
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