Antibody Patenting

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The aim is to publish innovative work appealing to practitioners, other users of IP systems and academics.

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Antibody Patenting

A Practitioner's Guide to Drafting, Prosecution and Enforcement

Edited by

Jürgen Meier

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Chapter 19

India

Mamta Rani Jha

§19.01 ANTIBODIES AS PATENTABLE SUBJECT-MATTER

Patent Law in India has undergone tremendous change over the years, making it possible to patent antibodies which are not naturally occurring and synthesized artificially, subject to fulfilling the requirements under the Patents Act, 1970 (hereinafter 'the Act'). In India, prior to 2005, only process patents were granted in respect of inventions relating to food, drug, medicines and 'substances produced by chemical processes' which included bio-chemical, biotechnological and microbiological processes.[1] Post 2005 amendments to the Act in compliance with India's TRIPS obligations, product patents became possible subject to meeting the criteria laid down under the Act.

Until 2002, the Indian Patent Office (IPO) did not grant process patents for inventions relating to (a) living entities of natural or artificial origin, (b) biological materials or other materials having replicating properties, (c) substances derived from such materials and (d) any processes for the production of living substances/entities including nucleic acids. The 2002 *Dimminaco AG v. Controller of Patents and Designs*[2] decision opened doors for the grant of process patents to inventions where the final product of the claimed process contained living microorganisms.

[A] Legal Framework

In India, product and process patents are possible for antibodies, subject to inventions fulfilling the three criteria of (1) novelty (2) inventive step and (3) industrial application.

The biggest challenge faced by the patentee in India is section 3 of the Act, which deals with inventions which are not patentable'. The relevant provisions under

1. *See* section 5, Patents Act, 1970, omitted *vide* Patents (Amendments) Act, 2005
2. IPLR 2002 July 255

section 3 while examining claims *qua* antibodies are section 3(c), 3(d), 3(e), 3(i) and 3(j). The relevant extracts thereof are:

> **Section 3(c):** 'The mere discovery of any living thing or non-living substance occurring in nature.'
>
> **Section 3(d):** '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 or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.'
>
> Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.'
>
> **Section 3(e):** A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.
>
> **Section 3(i):** Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.
>
> **Section 3(j):** Plants and animals in whole or any part thereof other than micro organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

[B] General Amenability or Exclusion of Antibodies from Patentability

The general objections and amenability are discussed below with reference to provisions of section 3 (see above).

Products such as antibodies, microorganisms, nucleic acid sequences, proteins, enzymes and compounds, which are directly isolated from nature (naturally occurring substances) are not patentable. However, antibodies which are not naturally occurring or synthesized in a laboratory, and processes of isolation of antibodies are patentable provided they meet the triple test of novelty, inventive step and industrial application.

Generally, the examiners interpret section 3(c) in a very narrow sense. It is their perspective that any antibody/polypeptide – even if it is a truncated part of some naturally occurring antibody/polypeptide – if has 100% similarity to the original, is construed as naturally occurring. Examiners usually allow modified or recombinant moieties. Thus, to counter the said objection, it needs to be demonstrated that the claimed antibody/polypeptide or nucleotide sequences are not naturally occurring and are modified using human intervention.[3] It is also important to demonstrate or

3. *See* Prosecution History of Patent No. 302196 [Application No. 5040/CHENP/2012 titled '*Antibody Binding to Human CSF-IR*', available publicly at www.ipindia.nic.in

distinguish a claimed antibody by highlighting the modifications by way of mutations or conjugation, for example.

In order to overcome the objections under section 3(c), following illustrative aspects may be part of the specification and claims:

- The invention relates to new monoclonal antibody, whose generation involves human intervention and it is not isolated from nature;[4]
- The combination of the light and heavy chain and constant regions are not to be found in nature;[5]
- The claimed combination of complementarity-determining regions (CDRs) in the monoclonal antibody are an unnatural construct formed by human intervention;
- The claim is for an isolated polynucleotide encoding the light and/or heavy chain of an antibody which is an unnatural construct formed by human intervention.

Section 3(d)

Section 3(d) is peculiar *sui generis* provision under Indian law, under which any new use of a known substance is not patentable unless there is enhanced known efficacy over the known substance. The Supreme Court of India in *Novartis v. UOI & Ors.*,[6] interpreted section 3(d) and held that enhanced known efficacy over the known substance has to be enhanced therapeutic efficacy and clarified that mere increase in bioavailability may not necessarily lead to an enhancement of therapeutic efficacy to overcome section 3(d).

While dealing with objections under section 3(d) of the Act, it has to be borne in mind that section 3(d) does not *ipso facto* apply to all chemical or pharmaceutical inventions. To apply section 3(d), it has to be established that the invention is a 'new form of a known substance' meaning that there has to be a known substance and the examiner has to identify the same. Although examiners frequently raise objections under section 3(d), if it is not a case thereunder, then an appropriate reply explaining how there was no known substance or derivative and thus section 3(d) is not applicable may be submitted.

However, if the invention does fall under section 3(d), then enhanced therapeutic efficacy data of a modified/derivative antibody over the prior known antibody should be provided. Examiners generally accept comparative data showing improved efficacy of the new substance/method *vis-à-vis* the closest prior art.[7] The IPO usually accepts

4. *See* Prosecution History of Patent No. 297285 [Application No. 797/DELNP/2012 titled '*Human Monoclonal Antibody Against S. Aureus Derived Alpha-Toxin and its Use in Treating or Preventing Abscess Formation*', available publicly at www.ipindia.nic.in
5. *See* Prosecution History of Patent No. 284359 [Application No. 171/MUM/2012 titled '*Anti-RHD Monoclonal Antibodies*' available publicly at www.ipindia.nic.in
6. AIR 2013 SC 1311
7. *See* Prosecution History of Patent No. 291864 [Application No. 4132/KOLNP/2009 titled '*Polypeptides, Antibody Variable Domains and Antagonists*', available publicly at www.ipindia.nic.in; Prosecution History of Patent No. 302148 [Application No. 2884/CHENP/2011

additional comparative data submitted during prosecution to overcome the objection under Section 3(d).

Section 3(e)

Typical objections under section 3(e) from the IPO are with regard to a composition comprising a combination of antibodies or an antibody with integers such as carriers or other substances.

A composition claim comprising an antibody is usually of two types. First, the composition may comprise the antibody as the only active ingredient along with inactive excipients. Secondly, the composition may comprise two active ingredients with an antibody being one of them.

Examiners routinely raises objections to composition claims construing prima facie composition claims to be mere admixtures resulting only in aggregation of properties.

In cases where there is only one active component in the composition, there could be scope to argue that such a composition is not contemplated under section 3(e).[8] However, where there are two active ingredients, which may fall under section 3(e), such objection can be overcome by submitting experimental data establishing that the claimed composition exhibits synergistic or unexpected properties[9] (i.e. a surprising effect beyond the sum of their individual effects). Further, the examiner may also ask for the ratio ranges of the individual components of a composition to make the claim more definitive.[10]

Section 3(i)

Although there is a prohibition under section 3(i) for processes for medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or animals, there is no bar for patenting a surgical, therapeutic or diagnostic instrument or apparatus.

Generally, the objections raised by the examiner pertain to the patentability of claims directed to a method of administration of antibody to treat a disease or detection of a disease. The case for a method of detection of a disease can be argued as long as it can be shown that such a technique is carried out *in vitro* and *ex vivo* and is only directed to detection of the disease and not towards rendering a human or an animal free of the said disease. A method of prognosis which is essentially the prediction of the occurrence of a disease based on presence or absence of certain markers can overcome the objection under section 3(e). Likewise, an antibody used

titled '*High Affinity Human Antibodies to Human IL-4 Receptor*', available publicly at www.ipindia.nic.in

8. *See* Prosecution History of Patent No. 302196 [Application No. 5040/CHENP/2012 titled '*Antibody Binding to Human CSF-IR*', available publicly at www.ipindia.nic.in
9. *See* Prosecution History of Patent No. 296780 [Application No. 1358/CHENP/2012 titled '*A Composition Comprising an Afucosylated ANTI-CD20 Antibody and Bendamustine*', available publicly at www.ipindia.nic.in
10. *Ibid.*

purely for research for detection of a protein using a molecular biology technique, for example, cannot be construed to be directed to rendering a human or animal free of disease and thus does not fall within the ambit of section 3(i).

Section 3(j)

Although, microorganisms are excluded from the non-patentability list, a conjoined reading with section 3(c) of the Act implies that only *modified* microorganisms, which do not constitute discovery of a living thing occurring in nature, are patentable subject matter under the Act.

Thus, any transgenic plant or animal that can be used to make antibodies is not patentable. Examiners are very rigid regarding the patentability of animal or plant derived cells. However, it may be argued that the established mammalian cell lines are propagated *in vitro* and not derived from an animal.

Biodiversity related issues

All intellectual property including patents based on research or information *qua* biological resources obtained from India can be granted only with the approval of the National Biodiversity Authority (NBA) established under The Biological Diversity Act, 2002. Under section 10(4) of the Act, disclosure of the source and geographical origin of a biological material used in an application for a patent is mandatory. Section 10 further requires that the microorganisms *qua* the invention be deposited at an International Depository Authority (IDA) under the Budapest Treaty before filing of the Indian application.

India being a party to the Budapest Treaty requires that in the particular case of inventions involving microorganisms, a deposit of biological material must be made in a recognized depository institution. The applicant need only deposit the biological material at one such institution, recognized by the IPO. Hence, to meet the sufficiency of disclosure requirement, in cases where the invention relates to biological material wherein it is not possible to describe the invention in a sufficient manner and further where it is not available to the public, the applicant shall deposit the material to an IDA. The deposit of the material shall be made no later than the date of filing of the application in India and a reference of the deposit shall be given in the specification within three months from the date of filing of the patent application in India.

[C] Required Distinction from Naturally Occurring Antibodies

As stated above, under section 3(c) of the Patents Act 'discovery of any living thing or non-living substances occurring in nature' is barred from patentability. However, there is no judicial pronouncement on the nature and quantum of human intervention/ modification – genetic and/or morphological – required to differentiate a living thing from one that already exists in nature. The argument as to whether isolation of biological material after extensive processing and technical intervention renders it outside the purview of 'living thing occurring in nature' and thus barred under section 3(c) is still to be settled.

There is no guidance whether usage of any term or qualifier aids or facilitates in the antibody patent prosecution. However, few best practices can be discerned from studying prosecution history and examiners' decisions, as stated above.

§19.02 ACCEPTABLE CLAIM FEATURES FOR DEFINING ANTIBODIES

[A] Functional Features

Functional antibody claims are claims that are directed to antibodies which have not necessarily been invented or created, but have been discovered or simply isolated without substantial human intervention and are capable of being used to perform alternative functions. Claims such as these are viewed differently in India primarily in view of section 3(c) of the Act. Therefore, if an isolated antibody binds to a target which is known in the art, such an antibody – in order to be patentable – might be considered to further fulfil the requirements of section 3(d) of the Act. In order to prove that a new form of a known substance has led to the actual enhancement of the known efficacy of such a substance, substantive test results and/or experimental data – evidencing surprising results and/or some especially desirable property of the known substance over the nearest prior art – has to be adduced as extrinsic evidence or otherwise. The only proviso is that there has to be a specific reference to the enhancement of efficacy of, for example, an antibody bound to a known target being claimed in the disclosure of the complete specification over related prior art. Such data can be submitted as extrinsic evidence and can help applicants in rebutting objections under this section.[11]

Therefore, a product or an antibody when defined by a functional feature is construed to fall under the 'use' category of claims as per the current patent practice. Examiners usually ask for structural features of the product to primarily characterize an antibody. However, functional features may further be included in the body of a claim as a further characterizing feature, especially in dependent claims.

[1] Target/Antigen

If a new protein has been discovered and a therapeutic use thereof has been disclosed, the IPO may in some cases grant claims related to a putative antibody against the said protein, particularly when an exemplification of such an antibody has been provided in the specification. Claims of this type would obviously have the broadest scope, as they encompass all future antibodies against the said target put into practice later on. The IPO's rationale is that the provision of a novel protein X enables a skilled person to produce an antibody against said protein.

Antibodies can have functional properties which are target-independent. The development of such a new functional property can thus give rise to a patent, the

11. Kumar, Swarup, *Patentability of Biological Material(s) – Essentially, Therapeutic Antibodies – In India* (2008) SCRIPT-ed, Vol. 5, No. 3, 2008 available at https://ssrn.com/abstract = 1578224

scope of which extends to all antibodies having such property, irrespective of the target they bind.

As regards a composition claim wherein the composition comprises a monoclonal antibody binding to antigen X, such a claim comprising a monoclonal antibody is mostly narrower than a claim that may cover a polyclonal antibody which has a wider ambit. The standard of interpretation of such claims is to primarily look at the intrinsic evidence or the disclosure in the specification. If the specification is unclear or silent as to the interpretation of a claimed feature, extrinsic evidence such as scientific definitions and common knowledge possessed by the skilled person at the priority date of the invention would apply.

Epitope targeted antibody claims

A patent can also be sought in respect of a second generation antibody by claiming specificity against a given epitope, or subdomain, of a target, provided that the said epitope has not yet been described as clinically relevant.

[2] Mode of Binding: Target Affinity, Binding Specificity, Epitope, Definitions via Reference Antibodies and Competitive Binding

Antibody based claims may also be defined by the mode of binding of antibody paratope with the epitope on antigen. Such type of claims may be drafted in the following manner: 'An antibody capable of binding X and blocking the binding of X to X-receptor.'

[3] Effect on Target

Another way to seek patent protection for a second generation antibody is to specify the latter through target-dependent functional properties, e.g., binding affinity against a given target, or competitive binding.[12] Such claims may be allowed by the IPO subject to meeting section 3 and require support with respect to sufficiency of disclosure.

Amongst other effects of the antibody on the target, the following types of effect may be defined in the claims:

- antagonistic/blocking or agonistic
- opsonising, neutralising
- monomeric or multimeric (dimeric, pentamer, etc)
- bispecific (binding two different types of antigens)

When defining the functional features in an antibody claim, it is not necessary to define a specific method of measurement for certain functional features in the claims. However, requisite support defining such functional features must be present in the specification along with the working example of the antibody with the said functional features and experimental support (if any).

12. U. Storz et al., *Intellectual Property Issues, Springer Briefs in Biotech Patents*, DOI: 10.1007/978-3-642-29526-3_1, The Author(s) 2012

[B] Structural Features

An antibody is primarily defined in the patent claims by its structural features and several levels of structural definition are possible.

[1] Molecular Topology: Antibody Types, Fragments and Antibody Constructs

In the case of a conventional antibody, the antibody can be defined by CDRs, which determine binding; by its light and heavy variable regions; or by its entire antibody sequence.

If the inventiveness of the antibody is based solely on the antibody having a higher binding affinity to the antigen than other known antibodies, the IPO may require the structural features, in particular, heavy and light variable domains to be specified in the claim because it recognizes that the choice of framework region residues can influence the antibody's final affinity. Regarding fragments, it has to be clearly established that they don't fall within the purview of 'naturally occurring substance' under section 3(c). Antibody construct based structural claims are also acceptable by the IPO.

[2] Amino Acid Sequences

[a] Full-Length Sequences of Antibodies

Structural claims reciting the full length sequences of antibodies are allowed by the IPO subject to section 3(c) of the Act.

[b] Sequences of Fragments, CDRs and Framework Regions

Sequence of fragments and framework region based structural claims may be allowed by the IPO subject to section 3(c) of the Act. As regards CDR based claims, as a rule, the IPO requires all six CDRs in the claim.[13]

[3] Chemical Modifications, Conjugation and Glycosylation

Apart from structurally defined antibody claims based on sequence listing, claims may also be defined by various chemical modifications[14] such as conjugation and glycosylation,[15] which have also found to be acceptable by the IPO.

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13. *See* Prosecution History of Patent No. 293079 [Application No. 3392/DELNP/2011 titled '*Improved Anti-CD19 Antibodies*', available publicly at www.ipindia.nic.in
14. *See* Prosecution History of Patent No. 305455 [Application No. 5305/DELNP/2012 titled '*Fusion Polypeptide Against EB Virus-Induced Tumor and Colicin IA Mutant*', available publicly at www.ipindia.nic.in
15. *See* Prosecution History of Patent No. 299247 [Application No. 8361/DELNP/2010 titled '*Methods and Compositions for Making Antibodies and Antibody Derivatives with Reduced*

[C] Cell Line Deposits and Process of Production

The deposition of a cell line, e.g. a hybridoma cell line or a transfected host cell line, may be an adequate way of specifying an antibody in order to avoid sequencing errors and typographical errors, or to provide enabling information for features which relate to post-translational modifications (e.g. unusual glycosylation patterns). The language of such antibody claims simply refers to the deposition nomenclature of the deposited cell line. Such claims are drafted in the following manner: 'The antibody produced by the hybridoma deposited under Accession No. 12345'.

As stated above, in the case of inventions involving microorganisms, a deposit of biological material must be made in a recognized depository institution. Further, in accordance with the Budapest Treaty, the applicant needs only to deposit the biological material at an IDA, recognized by the IPO.

§19.03 BREADTH OF CLAIMS AND SUPPORT BY EXAMPLES

Section 10(5) of the Act provides a general requirement that the claim(s) must be clear and succinct and fairly based on the matter disclosed in the specification. There is no special practice or threshold that has been adopted for examination of antibody claims. Thus, antibody claims are examined on a case by case basis, according to the aforementioned yardstick.

[A] Acceptable Breadth of Claims to Antibodies

Claims that define an antibody by sequence supported by the description generally fulfil the requirement of clarity and conciseness of claims mandated under the Act.

Generally, sufficiency requirements are met so long as at least one method for performing the invention covering the whole subject-matter claimed in the claims (not only a part thereof) is capable of being carried out by a skilled person in the relevant art without the burden of an undue amount of experimentation or the application of inventive ingenuity.[16]Antibody claims with therapeutic or diagnostic potential should be supported by defining their role for the target protein in a specific disease and should be substantiated by sufficient data. For specifications disclosing a wide range of unrelated diseases as the potential therapeutic target of a claimed gene or encoding protein, evidence should be provided to prove the claimed therapeutic or diagnostic use of the encoding protein.[17]

As regards the disclosure requirement vis-à-vis biological material, the specification should disclose the source and geographical origin of the biological resource used in the invention. Further, inventions using biological resources that are unavailable to the public, the same should be deposited in a depository authority listed on the website of the IPO. Additionally, the reference of the source of the biological material

Core Fucosylation', available publicly at www.ipindia.nic.in

16. *Raj Praksh v. Mangatram Chowdhury*, AIR 1978 Del 1
17. Bakhru, Rachna, Pandey, Suvarna, '*A Review of Recent Patent Opposition Cases*' publicly available at http://www.managingip.com/IssueArticle/3485799/Supplements/A-review-of-recent-patent-opposition-cases.html?supplementListId = 94724

should be made in the specification. The specification can be amended to include the source of biological material-during the prosecution as well.[18]

[B] Required Experimental Support for Claims to Functionally Defined Antibodies

As far the issue of disclosure is concerned (of specific amino acid sequences of the claimed antibodies), this requirement is something that is, more often than not, insisted upon by the IPO. Describing antibodies with respect to merely physical or chemical parameters (molecular weight or physical characteristics associated with such antibodies, for example) is generally not accepted by the IPO.[19]

The objection of lack of sufficient disclosure in case of functionally defined claims to antibodies may be met by referring to one to two examples along with relevant figures and experimental data, if necessary.

[C] Required Experimental Support for Claims to Structurally Defined Antibodies

It is generally insisted upon by the IPO that a specific reference to sequences of antibody chains, proteins or amino acids be included with the claims. The specific sequence IDs of the antibodies or nucleotide sequences being claimed must have been described sufficiently in the description so as to enable a person skilled in the art to identify and work upon such material. Otherwise, the 'lack of support' issue as well as enablement objections could be raised. Additionally, it must also be kept in mind that reference to more than one sequence IDs in the main claim is not accepted by the IPO unless it is possible to establish unequivocally that the multiple sequence IDs are correlated with another so that they constitute a *single inventive concept*.[20]

As far as the extent of disclosure of the variable chains of an antibody is concerned, it will depend on what is claimed, for example if a full length variable region is claimed and only a part of such a claim has been disclosed in the description, the claim will certainly be considered unsupported by the description. Similarly, it is preferred that the description includes a reference to both the heavy as well as the light chain CDR, even if it is only a heavy chain CDR that is claimed, so that a clear distinction can be brought out between them if necessary.

Examiners usually ask for the amino acid/nucleotide sequences and so on for antibody claims. Any experimental data that would support the claimed structural feature would be accepted by examiners such as sequencing data, DNA/protein modification data, X-ray diffraction data. Examiners usually look for the functional data for establishing superior technical effect.

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18. http://www.mondaq.com/india/x/799164/Patent/Patenting + Antibodies + in + India
19. Kumar, Swarup, *Patentability of Biological Material(s) – Essentially, Therapeutic Antibodies – In India* (2008) SCRIPT-ed, Vol. 5, No. 3, 2008 available at https://ssrn.com/abstract = 1578224
20. *Ibid*.

§19.04 SPECIFIC MEDICAL APPLICATIONS AND OTHER FOLLOW-UP INVENTIONS

As mentioned in section §19.01[A], claims involving medical applications have to overcome the bar under section 3(i). Given the overarching scope of the said section, claims for medical applications are often objected to and not granted.

[A] Treatment of Specific Diseases

In India there is a bar to patentability for method of treatment claims under section 3(i). Any method directed to rendering a human or an animal free of disease falls under the purview of this statute.

[B] Mode of Administration

Even the mode/method of administration of a drug/biologic is usually construed to be a method directed to rendering a human or animal free of disease. Hence, the examiner may raise an objection under section 3(i) to such a claim.

[C] Dosage Regimens

The dosage regimen or the method of dosing *per se* would not be allowed in India under section 3(i). However, a product, composition or a combination that crosses the threshold of patentability may further be characterized by the dosage regimen in a dependent claim. Some examiners may allow it and not raise an objection under section 3(i). However, patent practice in India varies from examiner to examiner and depends on each examiner's interpretation of the provisions.

[D] Specific Patient Groups

The method of treating a specific patient group using a claimed antibody would be objected to by most examiners under section 3(i).

[E] Specific Mode of Action

A product in India is defined by its essential technical features that are usually construed to be the structural features. The mode of action may be described in a dependent claim or as a secondary characterization in the body of the claim.

[F] Combinations with Other Active Ingredients

Combinations are allowed in India, subject to a higher patentability threshold. The examiner may raise an objection to a combination under section 3(d). To overcome this objection, the applicant has to show an enhanced therapeutic efficacy as compared to when the product is used alone. If the combination is formulated together, the examiner may further raise an objection under section 3(e), construing the claims

as a mere admixture. In such a case, the applicant shall have to show synergistic effect associated with such a combination when both the drugs are used in tandem.

[G] Specific Diagnostic Applications

Most examiners would raise a prima facie objection to a diagnostic application and bring it under the purview of section 3(i). However, it may be argued that the diagnostic application is carried out *in vitro* and *ex vivo*. Hence, there is no interaction with the patient and that the diagnostic application is not used *per se* in rendering a human or animal free of disease.

Only product and process claims are allowed in India and 'use' claims are generally not allowed. These include direct use claims, Swiss-type claims and second medical use claims. Second medical use claims worded in any form (Swiss-type, use claims or method of treatment claims) are not granted by the Indian Patent Office. Also, new use of known substances is clearly barred from patentability under section 3(d) of the Patents (Amendment) Act, 2005.

As regards 'kit' claims, such claims are usually not objected to since they are directed to a tangible entity in contradistinction to a method of treatment. The only further requirement with respect to such claims could be that of the inclusion of further 'constructional' features of the claimed kit. Further, there should be proper support for such constructional features in the accompanying description. Examiners sometimes object to kit claims and further construe them as a mere admixture and usually raise an objection preliminarily under section 3(e). Thus, any kit claim comprising an antibody and further components for putative treatment or diagnosis purpose may be objected to under section 3(e).[21] However, it may be argued that the kit *per se* is not an admixture as the components of a kit do not interact and produce any effect, if the components are packaged separately and further are submitted for consideration of the kit as a first application of a novel invention.

§19.05 ASSESSMENT OF INVENTIVENESS

The general principles regarding assessment of inventiveness are applicable to antibody patents equally and each case may be dealt with on its own description and supporting technical data.

[A] General Approach

Inventive step has been clearly defined in the Act by way of 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.'

21. *See* Prosecution History of Patent No. 297285 [Application No. 797/DELNP/2012 titled '*human monoclonal antibody against s. aureus derived alpha-toxin and its use in treating or preventing abscess formation*', available publicly at www.ipindia.nic.in

Accordingly, the test for inventive step is two pronged i.e. the claimed invention should involve technical advancement or qualification over the prior art and such technical advancement must not be obvious to the person skilled in the art as on the priority date.

Furthermore, the test of inventive step has been refined over time by the Indian courts. In one landmark decision in pharmaceutical patent litigation case involving *Roche and Cipla*,[22] the division bench at Hon'ble Delhi High Court laid down the following five-step test to determine whether an invention involves inventive step:

Step No. 1	To identify an ordinary person skilled in the art.
Step No. 2	To identify the inventive concept embodied in the patent.
Step No. 3	To impute a normal skilled but unimaginative ordinary person skilled in the art of common general knowledge at the priority date.
Step No. 4	To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various steps requiring multiple, theoretical, and practical applications.
Step No. 5	To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art and rule out a hindsight approach.

[B] Particularities Regarding Claims to Antibodies

In context of claims pertaining to antibodies, if the claimed invention relates to a polynucleotide/polypeptide having mutation(s) in a known sequence of polynucleotides/polypeptides, which does not result in an unexpected property whatsoever, then the claimed subject-matter lacks inventive step.[23] Therefore, it is essential to submit technical, experimental data to establish unexpected technical advantages/properties of the mutated sequence of such polypeptides.

It is seen that even when an antibody is described by its structural features, which are different from those of any known antibody, it may not be considered to be inventive. This is because the IPO considers it to be routine to prepare a polyclonal or monoclonal antibody (mAb) against any known antigen. Therefore, an antibody is considered inventive by the IPO only if it is unexpected that the antibody could be produced at all (e.g., if there are difficulties with isolation), or if the claimed antibody has unexpected, advantageous properties such as higher binding affinity, an unexpected antagonistic or agonistic effect, low cross-reactivity, or differential

22. *F. Hoffmann-La Roche Ltd & Anr. v. Cipla Ltd.* (2016) 65 PTC 1
23. *Guidelines for Examination of Biotechnology Applications for Patent*, 2013, as released by the IPO and available publicly at http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf

binding to monomer vs. dimer. However, the unexpected, advantageous property may depend on what is already known.[24]

§19.06 ENFORCEMENT AND SCOPE OF PROTECTION

There are hardly any cases regarding enforcement of antibody patents in India and therefore there is not much clarity on the scope of antibody protection. The litigation *qua* biosimilars is still awaiting resolution.

[A] Biosimilars

So far, Indian jurisprudence has not evolved any precedents on the scope of protection of antibody patents, particularly in context of biosimilars. However, the Hon'ble Delhi High Court, in the case of *Roche Products (India) Pvt. Ltd. & Ors. v. Drugs Controller General of India & Ors.*[25] had the occasion to elucidate upon the enforcement of biosimilars. The case in question pertains to the drug Trastuzumab, a monoclonal antibody used primarily in the treatment of HER 2 positive breast cancer, which was patented by Roche and marketed under the brands Herceptin, Herclon and Biceltis. After the expiry of Roche's patent in 2013, the defendants, Biocon, Mylan Inc. and Mylan Pharmaceuticals Pvt. Ltd., applied for and obtained marketing authorization for an alleged biosimilar of trastuzumab, namely, bmab/CANmab. Roche brought a court action against the alleged biosimilars in 2014. Roche was granted a secondary, formulation patent in relation to trastuzumab from the Controller General of Patents, in India, which lapsed on 3 May 2013. The plaintiff in this case sought an injunction against launching or introducing the drug by the defendants, an injunction from representing the impugned products as bio-similar until appropriate tests and studies were conducted including guidelines on similar biologics and an injunction from relying upon or referring to the plaintiff's trademark claiming similarity of the two drugs. However, the plaintiff did not allege infringement of its trade mark or its rights in respect of the expired patent in 2013. Its main concern was that without establishing the safety and efficacy as required under the Drugs & Cosmetics Act, Rules and Biosimilar Guidelines 2012, the defendants were not entitled to claim that it is a biosimilar drug of the innovator and would not be entitled to use the data of the plaintiff and give references in its package insert, carton and publicity materials by making the false statement and misrepresentation. The Court in this case upheld Roche's claims and restrained the Defendant companies from marketing their drugs as biosimilar of Roche's drugs pending the judgment of the trial.

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24. *See* Prosecution History of Patent No. 302273, Application No. 2250/DELNP/2011 titled '*A Multivalent, Dual Specificity Antibody Fusion Protein*', available publicly at www.ipindia.nic.in; *See* Prosecution History of Patent No. 302887, Application No. 6768/CHENP/2011 titled '*Anti-Human α9 Integrin Antibody and Use Thereof*', available publicly at www.ipindia.nic.in; *See* Prosecution History of Patent No. 293079 Application No. 3392/DELNP/2011 titled '*Improved Anti-CD19 Antibodies*', available publicly at www.ipindia.nic.in.
25. 2016 SCC Online Del 2358

The decision of the Single Judge has been challenged in appeal to the Division Bench, which has permitted the defendants to sell the alleged biosimilars in respect of Metastatic Breast Cancer, Early Breast Cancer and Metastatic Gastric Cancer and also maintain accounts. A final decision is awaited, and in any event a challenge to the Supreme Court is inevitable.

Interestingly, as a counterblast to the litigation, the defendants filed a complaint[26] in 2016 before the Competition Commission of India (CCI) alleging abuse of dominance by Roche and its affiliates in prohibiting entry of the bmab biosimilar in the market. Particularly, the defendants claimed that Roche was entering into vexatious litigations and writing frivolous communications to various authorities claiming that the bmab/CANmab biosimilar was hazardous to health, thereby impeding entry of the defendants in the market. In an order dated 21 April 2017, the CCI held that prima facie Roche's conduct was anti-competitive and directed an enquiry into the allegations. The same has since been challenged in appeal before the Delhi High Court by Roche. However, it is surely an interesting point for right-holders to be aware of when contemplating biosimilar litigation.

[B] Equivalence

There has been, so far, no ruling by the Indian courts on the interpretation of 'equivalents' of the claimed subject-matter which may be embraced by antibody claims.

26. *Biocon & Anr. v. Roche and Ors.*, Case No. 68 of 2016