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Patentability of Biological Material(s) - Essentially, Therapeutic Antibodies - in India

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Abstract

Indian patent practice and jurisprudence with respect to biological materials (including antibodies) is relatively new and thus not well-settled and/or uniform, unlike in the USA or Europe. In these circumstances, presenting a concrete picture re patenting of monoclonal antibodies in India is not feasible at this stage. Notwithstanding this constraint, this analysis presents various techno-legal issues that arise and which need to be addressed – vis-à-vis patenting of biotechnological inventions. Like any other field of invention, biological materials – such as therapeutic antibodies against a protein or genetic sequence – are generally considered patentable and qualify as an invention in India so long as such antibody gene sequence(s) or amino acid sequence(s) are (1) novel, (2) involve an inventive step, and (3) are capable of industrial application. However, notwithstanding

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compliance with these three cardinal requirements, an isolated biological material in contradistinction to a modified (genetically or otherwise) biological material is still considered prima facie not to fulfil the requirement of patentability by the Indian Patent Office (IPO). In short, merely discovered (isolated) antibodies are considered not to constitute patentable subject matter per se by the IPO even though such antibodies are identified by the specific functions they are capable of facilitating or carrying out. Conversely, if a biological material is one which has been (genetically) modified (preferably through substantial human intervention), it fulfils these requirements, and will likely be regarded favourably by the IPO. In fact, subject also to the satisfaction of the other technical and formal requirements laid down by the Patent Act 1970, such biological material will have a reasonable chance of qualifying as patentable subject matter.

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1. Introduction

India amended its *Patents Act 1970* in 2002 to meet its TRIPS obligations (amending, for example, the term of the patent to twenty years from what was previously seven years) which came into force on 20 May 2003. The third amendment of the *Patents Act 1970* - initially enacted by way of the *Patents (Amendment) Ordinance* 2004 - incorporated the provisions for granting product patent in all fields of technology, such as chemicals, food, drugs and agrochemicals. This Ordinance was replaced by the *Patents (Amendment) Act 2005* which is in force now having effect from the 1st of January 2005. Accordingly, the former s 5 (which envisaged that with respect to inventions relating to food, medicine, drugs or chemical substances, only patents relating to the *methods or processes of manufacture* of such substances could be obtained) of the *Patents Act 1970* was deleted, thereby introducing a product patents regime in the area of pharmaceutical and other chemical inventions in India. As far as the patenting of biotechnological inventions is concerned, the 2002 amendment added s. 3(j), which specified that plants and animals and any part of a plant or animal (excluding micro-organisms but including seeds) are not patentable. Likewise, varieties, species, and essentially biological processes used for production or propagation of plants and animals were also considered unpatentable.[1] Indian patent practice and jurisprudence with respect to the patenting of biological material (mainly antibodies) are relatively new and thus not so well-settled and/or uniform. In these circumstances, presenting a concrete picture – unlike the reasonably well-settled US and EPO practice – with respect to patenting of biological material in India is not entirely feasible at this stage. Notwithstanding the constraint referred to, an attempt to present the various techno-legal issues that arise and which needs to be addressed vis-à-vis patenting of biotechnological inventions has been made in the following paragraphs.

Like any other field of invention, biological materials – such as therapeutic antibodies against a protein or genetic sequence – are generally considered patentable and qualify as an invention in India so long as such antibody gene sequence(s) or amino acid sequence(s) are (1) novel, (2) involve an inventive step, and (3) are capable of industrial application. However, notwithstanding the compliance with these three cardinal requirements, an isolated biological material in contradistinction to a modified (genetically or otherwise) biological material is still considered prima facie not to fulfil the requirement of patentability by the Indian Patent Office (IPO). In other words, merely discovered (isolated) antibodies are considered not to constitute patentable subject matter per se by the IPO even though such antibodies are identified by the specific functions they are capable of facilitating or carrying out – unlike in many other jurisdictions, including those in Europe**.** For example, Rule 23c of the European Patent Convention (EPC) specifically states that even if a biological material existed or occurred in nature such materials are patentable as long as they are isolated from its natural environment or are produced by means of a technical process.

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[1] See R Ott, "Patentability of Plants, Animals and Microorganisms in India" (2004) 16 2 OKLA. J.L. & TECH. available at http://www.okjolt.org/articles/2004okjoltrev16.cfm (accessed 11 Oct 08).

Unlike the EPC, the expression "biological material" has not been defined in any of the sections of Indian *Patents Act 1970* or the rules thereunder. Some guidance may therefore be sought from the wording of the EPC which defines biological material as "any material containing genetic information and capable of reproducing itself".[2] If biological material is deposited that cannot replicate itself, but must be replicated in a biological system (e.g. viruses, bacteriophages, plasmids, vectors or free DNA or RNA) the aforementioned information is also required for this biological system. If, for example, other biological material is required (such as host cells or helper viruses) and which cannot be sufficiently described or is not available to the public, this material must also be deposited and characterised accordingly. In addition, the process for producing the biological material within this biological system must be indicated.[3]

However, the pertinent question to be answered with respect to the Indian scenario is whether all biological materials which satisfy the definition stated above can be considered patentable under Indian Law. In this respect it will be worthwhile to mention that the patenting of a living organism, or a process relating to manufacture of a product containing living organisms, was strictly considered not patentable in India until the year 2001, when the Kolkatta High Court altered the situation in the landmark *Dimminaco* judgment.[4] The Court held that since the subject matter claimed was directed to a novel process for the preparation of a vaccine under specific scientific conditions and the said vaccine was useful for the protection of poultry against contagious bursitis infection, there was no statuary bar to consider claims directed to a manner of manufacture as patentable even if the end products contained living organisms. This was the first time in the history of the Indian patent system that the patenting of a process for the production of a product containing living organisms was considered legitimate. The claims relating to living organisms (read microorganisms) *per se* were not considered patentable until the presence of s. 3(j) which provided, *inter alia*, for patenting of micro-organisms. This was achieved by s. 4 of Act 38 of 2002, which became effective from 20 May 2003.

Contrast this with the globally recognised US case, *Diamond v Chakrabarty*, which:

> *...affirmed the patentability of novel living organisms, and the USPTO has extended the broad ruling of this case to allow patents for novel seeds and plants (not just under the Plant Patent Act and the Plant Variety Protection Act), and for multicellular organisms (see In re Allen (1985) for a patented oyster, and U.S. Pat. No. 4,736,866 for a patented mouse, claimed as "a transgenic non-human mammal").*[5]

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[2] Rule 23(b)(3), EPC.

[3] See Part C, Guidelines for Substantive Examination, available at www.epo.org/patents/law/legal-texts/guidelines.html (accessed 11 Oct 08).

[4] *Dimminaco Ag v Controller of Patents & Designs and Others*, [2001] AID No.1.

[5] R Faber, "Landis on Mechanics of Patent Claim Drafting" (2005) at 26 of 32, available at http://www.djstein.com/IP/Files/Landis%20on%20Mechanics%20of%20Patent%20Claim%20Drafting.pdf .

For example, despite intense opposition to the patenting of human genetic material in Canada, the United States and Europe, isolated human elements- including nucleotide sequences- are generally eligible for patenting.[6]

One way to determine the patentability of biotechnological inventions[7] in general and biological material- specifically in India- is to venture deeply into the contents of s. 3(j) of the *Patents Act 1970*, which makes it possible to patent (at least) micro-organisms:

> *3. What are not inventions – The following are not inventions within the meaning of this Act … (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.*

It is apparent from the wording of s. 3(j) that *plants and animals in whole or any part thereof* and *essentially biological processes* are not considered inventions.[8] The expression "any part thereof", appearing in the first line of the section, is generally interpreted by the IPO in the broadest possible manner, including biological materials such as cells and tissues etc. However, the exceptions that are stated therein are microorganisms and processes which are not essentially biological, i.e. processes which involve *substantial human intervention*. There is a section among the Indian patent attorneys who are of a strong belief that the expression "any part thereof" in s. 3(j) ought to be defined– preferably with an explanation appended to the section. The apprehension- which is not unfounded- is that this expression is so open ended that it is liable to be interpreted in a manner that almost any biological material (for example DNA, RNA, protein sequences, antibodies, hybridomas, etc.) would be caught within its ambit. Fortunately, the IPO has yet to observe a situation where an invention has been rejected merely because it was claimed to be a genetic material (even though the patenting of tissues or cells of human beings or animals can be objected to under the foregoing section). Hereafter, a case study of the various aspects governing patentability of antibody related inventions is discussed.

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[6] See G Hagen & S Gittens, "Patenting Part-Human Chimeras, Transgenics and Stem Cells for Transplantation in the United States, Canada, and Europe" (2008) 14 *Richmond Journal Law & Technology*, available at http://law.richmond.edu/jolt/v14i4/article11.pdf .

[7] Rule 23(b)(2), EPC, defines "biotechnological inventions" as "inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used".

[8] In T 19/90 (1990) OJ 476, the EPO Board of Appeal agreed that the process claims for the production of transgenic non-human mammals through chromosomal incorporation of an activated oncogene sequence into the genome of the non-human mammal did not involve an "essentially biological process" within the meaning of Art. 53(b) EPC. The product claim for the genetically-manipulated animal included descendants not directly genetically manipulated themselves, but produced by the essentially biological process of sexual reproduction. The Board held that this was a product claim defined in terms of the process by which it was produced and that a product-by-process claim remains a product claim irrespective of the process it refers to.

2. Functional Antibody Claims

Merely 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[9] and are capable of being used to perform alternative functions. Claims such as these are viewed differently in India than in most of the other jurisdictions. Such divergent views have been adopted primarily in view of the contents of s. 3(c) of the *Indian Patents Act 1970*:

> *3. What are not inventions […] (c) the mere discovery of a scientific principle or the formulations of an abstract theory or discovery of any living thing or non-living substances occurring in nature.*[10]

From the manner in which this sub-clause is worded, it is clear that mere discovery[11] of any living thing or non-living substances occurring in nature is not considered patentable. Unfortunately, the expression "*occurring in nature*" is interpreted in the broadest possible sense in India. The general view adopted by the IPO is that an isolated- as opposed to modified- living entity is not substantially different from the form in which it existed in the nature. In other words the mere isolation of a living thing or a part thereof from its natural environment- without a modification (by genetic engineering or otherwise) that improves properties or increases efficacy of the claimed subject matter over the form in which it existed in its natural surroundings- does not render such an unaltered isolated entity patentable under the prohibition of s. 3(c).

A counter-argument to the view stated in the preceding paragraph is now considered. The moment a biological material or, more preferably, a part thereof is "isolated"[12] in the desired form from its natural environment, such material is no longer a *living thing occurring in nature* as envisaged in s. 3(c) of the *Patents Act 1970*. Additionally, quite often the material obtained by the process of isolation is in a raw state and thus needs to be processed further (e.g. purified by physical or chemical treatment) to render it industrially applicable. It can therefore be argued that the isolated material is not necessarily a "merely discovered living thing". Sadly enough, however, the fact remains that in order to secure a claim directed at biological materials (in general and antibodies) it is still preferable (read as 'necessary') in India that such material is a *modified* entity (e.g. genetically engineered) rather than being merely in an isolated and purified form.

On the other hand, 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 fulfill,

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[9] The expression "essentially biological process" appearing in s. 3(j) of the *Patents Act 1970* is interpreted to mean a process which does not involve substantial human intervention.

[10] As amended by the *Patents (Amendment) Act 2005* (hereinafter referred to as the Patent Act).

[11] In *Kirin-Amgen v Hoechst Marion Roussel*, [2005] RPC 9, it was held that the finding of a new substance or micro-organism occurring freely in nature is a discovery and not an invention.

[12] The process of isolation in some instances requires much more human intervention than in the actual process of genetic engineering.

inter alia, the requirements of s. 3(d),[13] which is clear in its import that the mere discovery of any new property or new use for a known substance is not patentable. The serious consequence of s. 3(d) is the establishment of a stable practice that prohibits secondary or tertiary uses of known substances. It is thus established that Swiss-type claims are forbidden in India (unlike in many other jurisdictions including Europe and New Zealand). In addition, the mere discovery of a new form of a known substance is also not considered to be patentable unless such a new form of the known substance evinces an enhancement in the already-known efficacy of that substance. This leads to an inference that a new form of a known substance will be deemed patentable if that new form actually does lead to an enhancement of the known efficacy of the known substance. In this respect it can be argued that, as far as biological materials are concerned, they are hardly ever referred to as a "substance". Additionally, there is almost an established view that s. 3(d) primarily deals with chemical (pharmaceutical, agricultural or any other chemical) substances, which is more evident from the fact that the explanation appended to this section exemplifies the different chemical forms of a substance which ought to be considered as the same substance. However, it has to be appreciated that at the end of the day, a protein or a DNA fragment or a pharmaceutical product prepared using such material is nothing substantially different than a chemical entity or congregation of chemical entities. Therefore it can be very accurately referred to as a biological substance- as opposed to a biological material- and hence such a substance will also have to fulfil the requirements of s. 3(d).

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,[14] 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. In *Novartis*, the Chennai High Court remarked:

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[13] Section 3(d), as amended, states 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 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, is not an invention. The explanatory notes state that, 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 substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy. Note that this is the provision which became the point of contention in arguably the most famous Indian patent litigation case: *Novartis AG v. Union of India*, [2006] W.P. No. 24759. For a detailed analysis of s. 3(d), see S Kumar, "Scope, Implications Of Section 3(d) Of The *Indian Patents Act* 1970 (As Amended)" (2007) *Swiss International IP Reporter - IP Watch,* available at http://www.ip-watch.org/weblog/index.php?p=637.

[14] With respect to the expression "efficacy" vis-à-vis pharmaceutical products, the Chennai High Court observed in the Novartis case, see note 13, that "…going by the meaning for the word "efficacy" and "therapeutic" […] what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/ having a good effect on the body? In other words, the patent applicant is definitely aware as to what is the "therapeutic effect" of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for."

> *As we stated earlier, due to the advanced technology in all fields of science, it is possible to show by giving necessary comparative details based on such science that the discovery of a new form a of known substance had resulted in the enhancement of the known efficacy of the original substance and the derivative so derived will not be the same substance, since the properties of the derivatives differ significantly with regard to efficacy.*[15]

Therefore, providing test and/or experimental data which evidences a surprising result and/or some especially desirable property of the invented composition over the nearest prior art is very helpful to evade an objection under s. 3(d). Such data can be submitted as extrinsic evidence and can help the applicants in rebutting the objection under this section. 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 on by most of the Indian patent officials. Describing antibodies with respect to merely physical or chemical parameters (molecular weight or physical characteristics associated with such antibodies, for example) is generally not appreciated by the IPO. This situation can in general be perceived to be quite different from the situation prevalent in the USA in view of the observation made by the Federal Circuit in Noelle's case, where it was held that, "as long as an applicant has disclosed a 'fully characterised antigen' either by its structure, formula, chemical name, or physical properties, the applicant can then claim an antibody by its binding affinity to that described antigen."[16]

To sum up, as far as Indian practice is concerned an isolated antibody bound to a known target – or a discovered target which has not been described in terms of sequence IDs – is most likely to be rejected by the by the IPO.

3. Sequence Specific Antibody Claims

As has been pointed out in the preceding paragraphs, it is generally insisted on by the IPO that a specific reference to sequences of antibody chains, proteins or amino acids be included with claims. Ideally, the broadest possible protection could be obtained by avoiding such an inclusion of references to specific sequences in the claims and thus it might not be prudent to include such specific references to sequence IDs (in some instances, at the risk of such claims being considered too broad or even vague) in the main claim at least. However, in the event that compliance with such a requirement is made mandatory by the final authority (the Controller) during the final stage of the prosecution of an application, such a reference could then be included, as broadly as possible, in the claim(s) in order to secure the eventual acceptance of such an application.

In these circumstances, it would perhaps be the best strategy to avoid including a reference to sequence IDs in claims to begin with and to do so only if such an inclusion assists with taking care of objections (such as to clearly distinguish an invention over prior art citations). Of course, the proviso is that the specific sequence

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[15] See note 13.

[16] See *Noelle v Ledermann*, (2004) 355 F.3d 1343 (FC).

IDs of the antibodies or genetic material being claimed must have been described sufficiently in the accompanying 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 the inclusion of a reference to more than one sequence of IDs – in essentially the main claim – is not appreciated by the IPO unless it is possible to establish unequivocally that more than one sequence of IDs is so correlated with another that they constitute a *single inventive concept*.[17]

As far as the extent of disclosure of the variable chains of an antibody is concerned, it will depend on what is claimed in the claims of a specification, i.e. 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 description. Similarly, it is preferred that the description includes a reference to both the heavy as well as the light chain Complementarity-Determining Regions (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.

4. Biological Function Requirement

When considering the inclusion and establishment of the biological function of a biological material, it is always better to include a broad range of biological experimental data – test result or efficacy data – both with *in vitro* as well as *in vivo* (essentially *in vitro* test data) to support the efficacy of a claimed biological material, e.g. an antibody over antibodies disclosed in the prior art. Further detailed test results could be adduced as extrinsic evidence during the course of the prosecution of an application. To sum up, it is invariably required that the specific function which a biological material is capable of carrying out is identified in the accompanying description as well as in the claims.

5. Biological Deposit

Submission and/or deposition of biological material to an International Depository Authority (IDA) is governed by s. 10(4)(ii) of the *Patents Act 1970*, which states:

> *10(4) Every complete specification shall - (a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed; ... Provided that – ... (ii) if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and fulfilling the*

[17] Section 10(5) of the *Patents Act 1970* reads: "[t]he 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."

> *following conditions, namely: (A) the deposit of the material shall be made not later than the date of filing the patent application in India and a reference thereof shall be made in the specification within the prescribed period; (B) all available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution; (C) access to the material is available in the depository institution only after the date of the application of patent in India or if a priority is claimed after the date of the priority; (D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.*

It is clear from the wording of this proviso that Indian law makes it mandatory to deposit biological material disclosed in an application with an IDA when: (1) such material and its operation or use and the method by which the invention is to be performed is not fully and particularly described in the specification, (2) the best method of performing such an invention is not disclosed therein, and (3) such material is not available to the public.

As far as the timing of the deposition of biological material is concerned,[18] it is clear from the wording of sub-clause (A) of the proviso that deposition of biological material – which does not fulfil the three criteria – shall be made no later than the date of filing the patent application in India and a reference thereof shall be made in the specification within the prescribed period. The prescribed period has been specified in Rule 13 (8)[19] of the *Patents Rules* 2003 as three months from the date of filing an application (in India). The other formal requirements are stated in ss. 10(4)(ii)(B), (C) and (D).

6. Enablement / Sufficiency / Disclosure Requirement

The issues of enablement and sufficiency of disclosure – irrespective of the field of technology – are dealt with ss. 10(4)(a) and (b)[20], which has already been quoted in the preceding paragraphs. Essentially, an invention is required to fully and specifically describe the invention and its operation or use and the method by which it is to be performed. With respect to the enablement requirement, an applicant is supposed to describe the best method of performing the invention which is known to the applicants and for which he is entitled to claim protection.

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[18] The corresponding rule with respect to the deposition of biological material in Europe is Rule 28(1).

[19] Rule 13(8) of The Patents Rules 2003 states: "[t]he period within which reference to the deposit shall be made in the specification under sub-clause (A) of clause (ii) of sub-section (4) of s 10 shall be three months from the date of filing of the application."

[20] Section 10(4)(b) states that "[e]very complete specification shall … disclose the best method of performing the invention which is known to the applicants and for which he is entitled to claim protection."

7. Method of Treatment Claims

As far as "method of treatment" claims are concerned, such claims (for example, a method for the treatment of disease X using an antibody having protein sequences a, b and c) are not considered permissible in India in view of the wording of s. 3(i) of the *Patents Act 1970*. From the language of s. 3(i), it is clear that a method of treatment for human beings or animals which renders them free of disease or increases their economic value (or that of their products) is not considered an invention within the meaning of the *Patents Act 1970*, as amended.[21] While Article 52(4) of the EPC specifies that what is prohibited is: "methods for treatment of the human or animal body by surgery or therapy"; there is no such further qualification stated in the s. 3(i) of the Indian Act, thereby leaving the doors open to a wider interpretation to include – aside from the specified categories – "other treatments".

Unfortunately, by virtue of an amendment to s. 3(i) brought out on 20 May 2003, the category "diagnostic, therapeutic" is also included within the definition in this section. The amended section, therefore, is clear that even diagnostic methods are precluded from the subject-matter considered as an invention. Moreover, it is important to note that there is an unambiguous difference between the language of this section and that of Article 52(4) of the EPC – in the latter, the expression "diagnostic method" is qualified by the wording "practised on the human or animal body". There is no such qualification stated in the s. 3(i) of *Patent Act 1970* thereby leaving the sub-clause open to an even wider interpretation that includes *any diagnostic process*. On the other hand, the last two lines of this section (unlike Article 52(4) of the EPC) specify a further qualification for which any of the processes stated therein should "render human beings or animals free of disease or increase their economic value or that of their products." Such wording, therefore, leads to the interpretation that unless a diagnostic method fulfills this precondition, it is not excluded from patenting.

Having said that, it is worthwhile to mention that no Examiner or even his or her superior officer (the Controller) has been, or is likely to be, sympathetic to this line of argument. The IPO's point-of-view is that since no diagnostic method on its own can actually render a human being or animal free of disease, the exception stated in the last couple of lines of s. 3(i) does not apply to "diagnostic method" at all. In the past, we have even attempted arguing for the allowance of diagnostic methods that are practised *in vitro,* i.e. not on a human body. However, even this argument has not been successful given that the section – unlike in Article 52(4) of the EPC – does not specify that only a diagnostic method practised on the human body is excluded. Given this trend there is almost no possibility for the allowance of "method of treatment" or "method of diagnosis" claims in India.

The only possible variant of such claims – which finds favour with most of the Indian Examiners – is to redirect such claims to the "kit" aspect of an invention. "Kit" 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

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[21] Section 3(i) states that "… 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" is not an invention.

to such claims could be that of the inclusion of further "constructional" features of the claimed "kit". This requirement is one that can be satisfied by including in the "kit" claim the basic constructional features of the kit at the very least – as long as there is proper support for such constructional features in the accompanying description.

8. Conclusion

As stated at the outset, the issues that relate to the patenting of biological material are relatively new to India. Additionally, standards or a standardised practice – unlike in the US or Europe – has yet to be satisfactorily established with respect to patenting or non-patenting of biological material including monoclonal antibodies. However, it is safe to say that as long as a claim of an invention is related to: (1) a novel and inventive modified (as opposed to isolated) antibody, wherein (2) such an antibody is identified by its protein or amino acid sequences at least in the description and, preferably, in the claims, and (3) such an antibody clearly and unambiguously identifies the specific (biological) functions it is capable of performing, i.e. by confirming that such an antibody is capable of industrial application, the IPO will generally consider such a claim to fall within the auspices of "patentable" claims. Therefore, subject to the fulfillment of the relatively broad general criteria stated above, the patenting of biological material in India is still decided more often on a case-by-case basis.