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A Portuguese and European perspective on telemedicine and e-health



Ricardo Costa Macedo and Diana Mâncio da Costa, of Caiado Guerreiro, Sociedade de Advogados, discuss the needed reinvention of medical care and how it is redefining the relationship between healthcare services providers and patients.



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Functional claiming in life science inventions in India

Manisha Singh & Pradeep Kumar Kamal, of LexOrbis, look to the USPTO, EPC, and EPO for examples and guidelines of the use of functional claiming to offer guidance for its use in India where the practice is still unsettled.

Structuring of claims which constitute a legal text, defining the scope of an invention of a patent application, is of paramount importance in protecting inventions. Claims crafted narrowly unnecessarily limit the protection, and result in infringers overcoming infringement by showing trivial variations. In contrast, broad claiming, defining a scope which is beyond what is encompassed by the disclosure, runs the risk of invalidation.

“**Runs the risk of invalidation.**”

'Functional claiming' is one such way of drafting claims with a much wider coverage with respect to structural components. The expression "functional claiming" refers to define the claims of an invention in terms of functional limitations of the structural component, rather than defining the structural component itself. Use of functional claiming is not confined to any particular field of invention but is associated with almost every field of invention in conjugation with its related terminology. Depending on the technology and the specific invention, functional claiming may be preferable and even unavoidable. At times, an invention (e.g., one software based) may be inherently functional or at least functional at the point of novelty.¹ Functional claiming, in one of its forms, is known to define inventions as a 'means for' performing a function, wherein expression "means for" refers to any broader generic representation of the structural element by using expressions viz. 'means for', 'mechanism for', 'component for', 'apparatus for', 'system for', 'member for', 'compound for', 'agonist for', 'antibodies for', 'probe for' etc. Such means plus function claims thus encompass a range of structural components that can perform the referred function. In life science related inventions, these structural components may be compound, active, biomolecule, nucleic acid, polypeptide, protein, cell lines, etc.

Functional claiming has always remained a dynamic concern among the different patent jurisdictions. While many of the patent jurisdictions recognize that there may be situations where an invention may be defined in functional terms,

there is divergent jurisprudence for acceptance of such claims among different patent jurisdictions. While there have been plenty of insightful judicial precedents dealing with functional claiming in United States and Europe, which provide guidance on enablement and indefiniteness issues of functional claims, pockets of grey area remain - which is inherent to dynamism new technologies and associated functional claiming.

The present practice of USPTO to consider and evaluate functional limitation, just like any other limitation of the claim, is the outcome of jurisprudence developed over more than 150 years. US Supreme Court in *O'Reilly v. Morse* (1854) invalidated a portion of Morse's primary patent for being defined as an effect produced by the use of electromagnetism distinct, from the process or machinery necessary to produce it.² In 1938, the US Supreme Court invalidated a patent in *General Electric Co v Wabash Appliance Corporation* because it claimed a tungsten filament in terms of its performance rather than its physical characteristics and did not adequately define the structural characteristics of the grains.³ The US Supreme Court in *Halliburton Oil Well Cementing Co. v. Walker* (1946) held that it is impermissible to use "conveniently functional language at the exact point of novelty".⁴ Post *Halliburton* case the U.S. patent statute was amended in 1952 by enacting § 112(f) to authorize means-plus-function claiming. The only suggested requirement that needs to be taken care in functional claiming is that the structure for performing the claimed function must be described in the patent's specification. Federal Circuit in *Williamson v. Citrix Online* case further guided for wider amplitude of functional claiming, by considering non-means claims as means-plus-function claims.⁵ However, claim reciting only function as the limitation to its scope without describing in the specification the corresponding structure for performing the recited function are often considered invalid being indefinite.⁶

European Patent Convention (EPC) on the other side stipulates that the claims should define the matter for which protection is sought in terms of technical features, and does not provide any specific provision for facilitating functional claiming.⁷ However, EPO, in its Guidelines for Examination, permit inclusion of functional features in a claim, provided that a skilled person would have no difficulty in providing some means of performing said function without exercising inventive skill. The approach of EPO is rather more flexible and lenient one as compared to USPTO.⁸ EPO specifically considers one subset of functional claiming to be acceptable upon satisfaction of certain prerequisite. Claims



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Résumés

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¹ Recalibrating Functional Claiming: A Way Forward, *Landslide*, Vol. 12, No. 3, January/February 2020, by the American Bar Association;

² *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1854);

³ *General Electric Co v Wabash Appliance Corporation* (304 US 364 (1938));

⁴ *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 12-13 (1946);

⁵ *Richard A. Williamson v. Citrix Online, LLC* (Fed. Cir. 2015);

⁶ *Ex parte Miyazaki*, PTAB (2008);

⁷ Rule 43 (1), Chapter II, Part III, Implementing Regulations to the Convention on the Grant of European Patents, The European Patent Convention;

⁸ T 0068/85, EPO;

⁹ F-IV 4.10 Guidelines for Examination, EPO;

only defined in terms of a 'result to be achieved' are accepted, contingent to satisfaction of conditions that it is not possible to formulate the claim more precisely without unduly restricting the scope of the claims and that it is possible for the skilled person to verify the result without undue burden.⁹

Indian patent law and practice on functional claiming is an unsettled one with no jurisprudence. While there is no statutory bar on claims with functional language, claims with only functional limitations are outrightly considered to lack technical features by Controllers/Examiners of Indian Patent Office. This approach may be connected to existing legal sources viz. The Patents Act, 1970 (as amended), Manual of Patent Office Practice and Procedure, different Guidelines for Examination of Patent Applications and judicial precedents, all of which either fail to recognize functional claiming or provide leeway. The statutory definition of invention provided under Section 2(1)(j) of the Patents Act, 1970 (as amended) "'invention' means a new product or

process involving an inventive step and capable of industrial application" is wide enough to accommodate functional claiming. The definition only necessitate that an invention should be a new product or a new process involving an inventive step and capable of industrial application. However, Section 10(4)(c) of the Indian Patents Act, 1970 (as amended) which require the claim(s) to define the scope of the invention for which protection is claimed, upon its interpretation may impede claims defined only with functional limitations.¹⁰ The interpretation of Section 10(4)(c) of the Act may be attributed to an Indian patent jurisprudence having tendency to make literal interpretation of claims. This is in contrast with practice of USPTO and EPO which consider structural features recited in the description and place reliance on the ability of a skilled person to infer such structural features. Another, limiting reference comes from the Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, which consider that functional claiming should be discouraged because such claims lead to confusion regarding the scope of the invention and that in most of the occasions such claims encompass a scope which is inconsistent and much wider to the scope afforded by the descriptions.¹¹ Owing to specific absence of permissible or qualifying requisites for functional claiming in legal sources, Indian Patent Office (IPO) practice on functional claiming is considerably restrictive than that of the USPTO and the EPO. Claims defined only with functional limitations are often objected by Indian Patent Office for lacking technical features, being unclear and indefinite in their scope. IPO practice related with claim definitiveness require claims to be defined by at least the inventive feature.¹² This may be due to a relatively lower degree of reliance placed on person skilled in the art for the purpose of determining the scope of claims for evaluating definitiveness and enablement requirement as compared to USPTO and the EPO.

Inventions in life science often relate to complex biomolecules, which at times may be difficult to depict by words. This is the reason claims with simple reference to sequence in form of sequence ID is universally accepted. Owing to the complex nature of inventions in life sciences and considering the need to protect the invention with a scope sufficient to cover the trivial structural changes, claims with functional limitations hold specific significance. Functional claims in life sciences, like other claims may, relate to a protein, polypeptide, antibody, or gene. Such functional claims in their extreme form may be considered as 'reach-through' claims, if there exists only a functional relationship among the different



Structural components may be compound, active, biomolecule, nucleic acid, polypeptide, protein, cell lines.



biomolecules, but there is no limitation to rescue a person of ordinary skills to derive the entire set of molecules covered by the scope of such claims.¹³ Such reach-through claim, like other claims, may be a product claim, a process claim, or a product by process claim. For example, an invention related to identification of peptide, which modulate the activity/function of an important gene/protein, may be drafted as "molecules/agent capable of modulating the activity/function of particular gene/protein" or as "molecules/agent capable of identifying particular gene/protein". Such claims would literally cover all molecules that modulate the activity of the gene/protein as identified in said invention and if no structural limitation is considered for construing the scope of claim, it would also cover future molecules that would perform the same function, or that are possible in theory. The same approach may be translated to process claims, wherein process elements are not defined by their structure but are defined by its function i.e., ability to modulate the expression of a protein or gene. A claim related with production of important biomolecule may be drafted as reach-through claim with a language "A cell culture capable of producing biomolecule with amino acid sequence 1". In such claim if there happens to be no limitations (process or product) related with cell culture, the claim encompasses production of biomolecule with amino acid sequence 1 using any cell culture. There is still another type of functional claims, which are not absolutely 'reach-through' claims but are considered as 'quasi reach-through', as these claims seek to protect molecules, which are not defined by structure but are comparatively confined to be derived using a particular protein or gene.¹⁴ A claim to a monoclonal antibody against particular protein without structurally defining the antibody, a probe against nucleic acid or amino acid sequence, a cDNA sequence of a gene are examples of quasi reach-through claiming, since such antibodies, probes and cDNA sequences can be reasonably presumed to have been obtained in routine manner by using well-known techniques.

The device of functional claim allows a patent drafter to cover a potentially broad class of structures with a single claim limitation. For example, a claim with broad or generic structural and functional limitation "A peptide capable of treating a cancer", the generic structural limitation construed along with function limitation "capable of treating a cancer" would cover a diverse range of peptides that may interact with diverse target for treating a cancer. Considering that such claim also has additional limitation defining the target of such peptide, such claim

¹⁰ Section 2(1)(j); Section 10(4)(c) Indian Patents Act;

¹¹ Paragraph 11:13, page 40, Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals (2014);

¹² Paragraph 05.03.17 k), page 44, Manual of Patent Office Practice and Procedure, Version 3.0 (2019);

¹³ F-III 9, Guidelines for Examination, EPO;

¹⁴ Reach-through Patent Claims in Biotechnology: An Analysis of the Examination Practices of the United States, European and Japanese Patent Offices;

on its face would even cover peptide that may not yet have been invented but could interact with said target for treating cancer. Nevertheless, said claim, along with additional limitation defining the target of such peptide, is likely to be considered as 'quasi reach-through' claims, depending upon simplification of techniques involved therein to reach the possible products.

Owing to importance of such claims in life science and the existing vacuum in Indian legal texts to steer functional claiming, Indian Patent office may resort to guiding jurisprudence of US and EP and come up with guidelines to consider functional claiming in a right perspective. Meanwhile, inventions proposed to be protected in India must avoid claims defined only by functional limitations, and must at least define structural feature responsible for ingenuity of subject invention in the claims itself. In other words, the claim language by itself should be sufficient to convey a person of ordinary skill in the art about the structural limitations or process steps encompassed by said claim. The invention must be drafted with sufficient number of dependent claims reciting structural features leading to functional limitation, for the fallback position. This would eventually help in addressing the issues related with the clarity and indefiniteness

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of the scope of claims during prosecution in general and in particular during invalidation/ infringement proceedings, as the Indian courts have preference to infer the scope of claims by considering the limitation recited in the claims. The description should include sufficient examples to cover range of structural limitations that can perform the claimed functional limitation.

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