In re Harnisch 631 F.2d 716 (C.C.P.A. 1980)
(United States Court of Customs and Patent Appeals)

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Case summary

The United States Court of Customs and Patent Appeals (CCPA), which was the predecessor of the United States Court of Appeals for the Federal Circuit reversed a decision by the United States Patent Office (USPTO) to reject a patent application on the basis of alleged improper use of the "Markush claims" format. The CCPA confirmed unity of the claimed invention at issue and therefore considered the Markush claims format as being properly used.

The facts

The appellant, Harnisch, applied for a product patent on a group of coumarin compounds used as dyestuffs for synthetic or natural fibers as well as plastics and liquids. Instead of claiming each chemical entity contained in the group by its structure, Harnisch limited his claims to a number of general structural characteristics shared by all coumarin compounds, leaving a large number of compounds unspecified ("Markush claims", in reference to the first user of this claims format). The USPTO rejected the application for failing to meet the USPTO's own requirements for properly using the Markush claims format. Harnisch appealed to the CCPA. The CCPA reversed the decision of the USPTO.

The legal issues

The main issue in this case was the appropriate application of the requirements to admit Markush claims format as laid down in the USPTO's patent examination guidelines. Markush claims are a sub-category of structural claims. This claims format enables the inventor to claim a large number of unspecified compounds along with a specified general structure and some specified alternatives available under that structure. Unspecified elements may have certain structural differences and untested properties as compared to the specified elements. Their properties are only theoretically inferred from the equivalence with specified compounds within the claim. Depending on the extent to which they are admitted, Markush claims may result in product patents with a very broad scope of protection. The admissibility of Markush claims is not addressed under TRIPS. Before the EPO and USPTO, such claims are generally admissible if all claimed alternatives share a common structure and have a common property or activity.[1]

[1] For more details on this claims format, see WHO-ICTSD-UNCTAD, "Guidelines for the examination of pharmaceutical patents: Developing a public health perspective." Working Paper, by Carlos M. Correa, Geneva, January 2007, pp. 12-14 (http://www.iprsonline.org/resources/docs/Correa_Patentability%20Guidelines.pdf) .

In the present case, the Court specifically examined whether the recourse by the appellant to the use of the Markush claims format was in disregard of the administrative requirement of unity of invention. Many national patent laws provide that one patent application can only cover one invention or a group of closely related inventions. The rationale behind this rule is to facilitate the classification of the patent by the patent office and, importantly, to prevent applicants from avoiding multiple patent fees by filing only one application for a multitude of unrelated inventions. The CCPA in this context emphasized the fact that all claimed alternatives of the appellant's invention were coumarin compounds of similar structure and all may be used as dyes. Accordingly, the Court decided that Harnisch's application was in line with the unity of invention requirement and the use of the Markush claims format was thus admissible. The CCPA affirmed precedent according to which the examination of similarity in structure and properties should not be carried out too rigorously, as there would always be certain differences among the compounds of a claimed group. Rather, an overall assessment should suffice, and the characterization of several compounds as belonging to the same genus should not be "repugnant to scientific classification."[2]

The Court stated that in the past, other courts had raised doubts about the conformity of the Markush claims format with other patent law requirements, in particular the requirements of definiteness and enablement disclosure. The definiteness requirement in national patent laws, which is not expressly referred to in TRIPS, obliges a patent applicant to distinctly claim the subject matter of a patent in a way that defines its boundaries. Markush claims could be problematic in that respect, as they do not specify every claimed compound, but define the boundary of an overall group of compounds.

In addition, the disclosure requirement, which is stated in Article 29.1 of the TRIPS Agreement, requires applicants to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. The Markush claims format leaves a substantial number of compounds undisclosed. The claims only refer to an overall common structure and a few examples of sub-elements. In the areas of chemistry and biotechnology, the development of sub-compounds with certain properties from an overall common structure may be difficult to predict, thus making it difficult, if not impossible for a skilled expert to make the unspecified compounds based on the patent document. The patent applicant is likely to counter such alleged lack of enabling disclosure by arguing that the undisclosed alternatives will be predictable for a skilled expert to develop. However, such approach could call into question the non-obvious nature of the undisclosed elements, arguably making them fail the non-obviousness test. The patent applicant may thus be caught between the enablement/disclosure requirement on the one hand and the inventive step test on the other. Despite these conceptual problems related to the use of Markush claims, the CCPA limited its analysis to the unity of invention requirement and reversed the decision of the USPTO to refuse the patent grant.

[2] See the decision of the CCPA at p. 5.

Points of significance

- The extent to which Markush claims are admitted lies entirely within national discretion. This format is particularly used in countries interested in promoting the R&D-based pharmaceutical industry. In developing countries, whose pharmaceutical industries depend on generic production, broad patent claims as promoted by the use of the Markush formula could result in inappropriate blocking effects for generic competitors. The boundaries of the claimed groups would not be entirely clear for competitors, possibly generating a chilling effect for fear of patent infringement. In addition, the patent, once fallen into the public domain, would be difficult to carry out for a competitor, due to the lack of precise disclosure of the claimed elements.
- The judiciary may play an important role in limiting the use of Markush claims. Based on the enablement disclosure requirement (Article 29.1, TRIPS), the courts may reject claims that extend to elements of the invention that are not specified and supported by the examples given in the patent document. Where unspecified elements are obvious to carry out, the court may in certain cases reject the inventive / non-obvious character of the compound at issue.
- If Markush claims are generally admitted under national law or patent examination guidelines, the courts have to proceed their analysis on a case-by-case basis.

Key words
Markush claims; unity of invention; disclosure; enablement; definiteness of claims.

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