

Avoiding pitfalls obtaining inhalation patents at the European Patent Office

Patent specification must be detailed and commensurate in scope with the claims for patent allowance

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Summary

As in any field, obtaining a patent from the European Patent Office (EPO) for an inhalation product is challenging. Any invention must meet the three requirements to qualify for patent protection: (1) it must be new, (2) it must involve an inventive step, and (3) it must have an industrial application.[1] If the invention fails to meet just one of these requirements it is not patentable. It is also critical that the description of the invention meet the requirement of being sufficiently clear and complete, as to allow it to be carried out by a person skilled in the art.[2] In other words, an application must explain the invention in sufficient detail to allow others in the field to replicate the invention. Recent decisions of the EPO Board of Appeal (EPO Board) reveal that one of the more common problems encountered by inventors in the inhalation field is the failure to include a sufficient description of the invention in the original application. When the EPO reviews patent applications it does so from the perspective of one possessing skill in the art. For applications related to inhalation products, the EPO will review them from the perspective of one skilled in the inhalation field. This makes it critically important that the application include a description that others in the inhalation field can use to practice and replicate the invention. Additionally, the claims that constitute the protected property must be clear, concise and fully supported by the description.[3] Claims that differ in scope with the invention's description have also been revoked by the EPO. Recent inhalation cases demonstrate that taking care in drafting a detailed description of the invention and matching the scope of the claims to that description are critical to successfully patenting an inhalation invention at the EPO.

Recent Board of Appeal decisions on inhalation products

Several recent EPO Board decisions on inhalation patents give insight into how the EPO reviews the application and claims through the view of one of skill in art and how that affects patentability of the invention. The representative claims discussed are for illustrative purposes and any rejection of individual claims did not automatically result in the patent being held invalid.

Lack of sufficient novelty or clarity

The EPO Board has revoked claims for lack of novelty and for lack of clarity involving a patent directed to using a new manufacturing method to create particles with characteristics especially suitable for pulmonary drug delivery.[4] One of the claims at issue was the following product-by-process claim:

> 9. Particles suitable for use in pulmonary drug delivery by inhalation, which particles are spherical and crystalline, have a rough surface and incorporate an active agent, the particles being obtainable by a method according to any one of claims 1 to 8.[5]

During the appeal proceeding, the proprietor of the patent argued that the particles in claim 9 were different from particles in prior art compositions because the claimed particles had rough surfaces and their particle size distribution was narrow.[6] The EPO Board rejected these arguments. First, with respect to the particles having a rough surface, because there was no definition of the term "rough" in the application, the EPO Board found that term must be read with its broadest possible meaning.[7] The EPO Board reasoned that because, under normal circumstances, no particle would be expected to be perfectly smooth, all the claimed particles would have some degree of roughness and therefore be indistinguishable over prior art particles.[8]

Second, the EPO Board rejected the proprietor's narrow particle size distribution argument. The EPO Board recognized that a narrow particle size distribution of the particles was shown in figures in the patent, however, there was no explicit mention of the particle size distribution in the claim.[9] Without a mention of the particle size distribution in the claim, the particle size distribution could not be considered a distinguishing feature limiting the claim[10] Ultimately, the EPO Board concluded that because neither the surface roughness nor a specific "narrow" particle size distribution distinguished the claim features over known prior art particles, the claim was unpatentable because it lacked novelty.[11] Had the proprietor included a specific definition of roughness and an explicit particle size distribution range in the claim language itself, the narrower claim would have matched the description of the invention, and the claim would have stood a greater chance of being allowed.

In the same proceeding, the proprietor also submitted an auxiliary claim further narrowing the claim by adding the feature "relative degree of crystallinity being 90% or higher." To determine crystallinity, the patent mentioned use of x-ray powder diffraction and use of a reference powder having crystallinity of 79%. However, the EPO Board rejected the claim, finding that the methodology for determining the relative crystallinity was not sufficiently identified or described in the patent specification.[12] In particular, the methodology failed to identify how the relevant diffraction maxima were to be selected, how the estimation based on the broadening of the diffraction maxima was to be conducted and how the reference sample was to be chosen.[13]

The EPO Board was also troubled by the description of the reference sample in the application. The example in the patent specification showed the reference powder having a crystallinity of only 79%.[14] The EPO Board reasoned that one having skill in the art reading the claim would normally assume that the sample chosen as a reference material would have a high degree of crystallinity and would be set at 100% relative crystallinity for purposes of comparison.[15] The problem, as recognized by the EPO Board, is that if the particles in the claim are to have a "relative" crystallinity of more than 90% to a reference powder that itself has only 79% crystallinity then almost any particle will meet that requirement making the "90% or more" term not a limiting feature at all.[16] Given this lack of detail means that the skilled person would not be in a position to determine if a given sample meets the requirement that the relative degree of crystallinity be 90% or higher.[17] This failure resulted in the claim being rejected for lack of clarity.[18] Patent applicants must be sure that the methodologies and data disclosed in the patent description actually support any limitations added to the claims.

Insufficiency of disclosure

Likewise, the EPO Board revoked claims for lacking sufficiency of disclosure similarly involved a composition patent for inhalation particles[19, 20] One of the claims at issue was:

> 1. Particles for use as a carrier in the preparation of pharmaceutical formulations for the pulmonary administration of micronized active ingredients by means of a powder inhaler, wherein the median diameter of said particles is greater than 90 μm, *the surface rugosity is less or equal to 1.1 upon determination of the fractal dimension as described on page 14, line 15-page 15, line 11* and their surface is coated with an additive selected from lubricants, anti-adherents and soluble polymers. [Italics added by this author.]

The key feature of the claimed invention was the surface rugosity of the particles used in the composition. The issue before the EPO Board was determining if there was sufficient disclosure to understand the term "rugosity." The claim explicitly stated that rugosity was to be determined using the methodology described on pages 14 and 15 of the patent application. However, the methodology described was a new method, created by the inventors using a scanning electron microscope (SEM). The question arose as to whether the information contained in the application would on its own enable a person of skill to determine rugosity.[21] There was no prior art showing an earlier use of the methodology to determine rugosity.[22] The EPO Board doubted the reliability of the new measurement methodology because, among other reasons, there was evidence that the same particle could be considered to have the required rugosity or not depending on the magnification used for acquiring the image of the particle surface[23] The EPO Board laid blame on the proprietor for having deliberately decided to use its own, uncommon method for determining rugosity and placed a duty on the proprietor to provide full information for implementing the procedure.[24] As the EPO Board instructed:

> In general terms, when the issue of sufficiency concerns the description of a method for determining a parameter, the less common the method the more accurate the information provided in the description should be.[25]

Because of the fundamental lack of technical information concerning the determination of rugosity, the EPO Board rejected the claim for lack of clarity.[26] When a truly novel method is used with an invention, the patent applicant has a higher burden to disclose in the patent all the information necessary to practice the invention. A novel method requires the person of skill to rely primarily on the teachings of the patent, so the EPO will require all important pieces of information, such as instrument settings, to be clearly and sufficiently disclosed in the patent to avoid uncertainties and guesswork.[27]

Extending beyond the content of the application

Two appeals involving related patents for use of nitric oxide (NO) to treat pulmonary vasoconstriction and persistent pulmonary hypertension in newborns resulted in patent claims being revoked because many of the claims extended beyond the content of the original application.[28] One example of a revoked claim was Claim 17 of EPO Patent No. 0 786 264 that follows:

> 17. A gaseous mixture containing nitric oxide, oxygen and less than 1 ppm NO_2, for use in therapy.[29]

The EPO Board rejected this claim because the description in the original application was limited and focused the invention specifically on the use of NO to prevent or reverse the condition of acute pulmonary vasoconstriction.[30] Additionally, the gaseous mixture as defined in the patent included nitrogen N_2 gases.[31] The claim, however, went well beyond the treatment of pulmonary vasoconstriction to include other conditions and there was no basis in the application for use of the gaseous mixture which did not necessarily contain N_2.[32] The EPO Board reasoned the claim as drafted would cover any therapeutic use of NO to treat any condition, even though the only medical condition disclosed as treated in the parent application as filed was pulmonary vasoconstriction with different etiologies.[33] The EPO Board's rejection of the claim was based on the conclusion that the claim contained added matter and was not commensurate in scope with the patent's description.[34] Because the claim was broader in scope than the invention's description in the patent, it was doomed to fail.

Shortly thereafter, the EPO Board rejected similar claims from the same proprietor in a separate but related application directed to treating persistent pulmonary hypertension in newborns (PPHN) because the claims extended beyond the application as filed.[35] An example of such a claim follows:

> 1. Use of a gaseous mixture consisting of NO and N_2 for the production of an inhalable medicament for treating pulmonary hypertension in a patient with persistent pulmonary hypertension of the newborn.

Again, the EPO Board reading the claim as one of skill in the art found the description in the original application linked the therapeutic treatment of PPHN to its specific effect of pulmonary vasodilation.[36] This effect was absent from the claim, resulting in a claim that encompassed forms of treatment of PPHN which were not disclosed in the application.[37] Thus the claim was ruled invalid for extending beyond the application because the claim could cover the use of NO and N_2 for any treatment of pulmonary hypertension in newborns regardless of whether the medication was acting to cause pulmonary vasodilation.

Interestingly, the EPO Board did allow an auxiliary claim that substituted the general treatment language with specific language related to acute pulmonary vasoconstriction described in the patent.[38] Once the patent proprietor narrowed the claim and limited it to the specific treatment identified in the application, it was perfectly matched to the invention's description, making it allowable.

Also of note, the EPO Board throughout its decisions when reviewing the arguments put forth by the parties, repeatedly recognized a clear distinction between lungs of newborns suffering from PPHN and lungs of older patients suffering from other pulmonary issues.[39] The EPO Board rejected a number of the parties' arguments by refusing to equate data generated from other patient populations with the newborn patient populations.[40] This is another example of why the description in the patent must disclose sufficient treatment and patient data to support the scope of the claims, especially with method-of-treatment patents.

Conclusion

When the EPO reviews inhalation patents and applications, it views the description and claims from the perspective of a person having skill-in-the-art. Accordingly, the application must contain a detailed description of the invention that will allow one of skill to understand and practice the invention. Additionally, the scope of the claims must match the invention described in the patent. If the claims cover more than the invention's description, the claims will be rejected for extending beyond the application. Including a detailed description of the invention and matching the scope of the claims to that description will improve the likelihood of successfully acquiring an EPO patent on an inhalation invention.

References

References in this article are publically available materials, all of which can be obtained by copying the reference into the search box provided at the top of the EPO's website home page at www.epo.org.

1. Art. 52 (1) European Patent Convention (EPC)

2. Art. 83 EPC

3. Art. 84 EPC

4. EPO Patent 1 242 048, Inhalation particles, October 26, 2005.

5. Claims 1 through 8 described the inventive method for preparing the particles by suspending droplets in a carrier gas and then passing them through a heated tube flow reactor under pressure.

6. Case Number T 1392/09, Board of Appeal EPO, Decision of November 13, 2013 at p. 8.

7. Id. at p. 11

8. Id.

9. Id. at p. 14

10. Id.

11. Id. at p. 15

12. Id. at p. 16

13. Id. at p. 17

14. Id.

15. Id.

16. Id. at p. 18

17. Id.

18. Id. at p. 18-19

19. Case Number T 0602/10, Board of Appeal EPO, Decision of June 24, 2014.

20. EPO Patent 1 196 146, Powder particles with smooth surface for use in inhalation therapy, September 13, 2006.

21. Id. at p. 9

22. Id.

23. Id. at p. 11

24. Id. at p. 12

25. Id.

26. Id. at p. 13

27. Id. at p. 12

28. Case Number T 0434/12 (Case No. T 0434/12), Board of Appeal EPO Decision of September 18, 2013; Case Number T 0809/10 (Case No. T 0809/10), Board of Appeal EPO, Decision of October 10, 2013.

29. EPO Patent 0 786 264, Devices for treating pulmonary vasoconstriction and asthma, October 31, 2007.

30. Case No T 0434/12 at p. 67.

31. Id.

32. Id. at p. 68

33. Id. at p. 67

34. Id. at p. 68

35. Case No. T 0809/10.

36. Id. at p. 40

37. Id.

38. Id. at p. 44

39. Id. at pp. 37, 42, 50, 51

40. Id.

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