Journal of Intellectual Property Rights
Vol 19, March 2014, pp 97-103

Oppositions against European Patents: Three Successful Examples of Oppositions Lodged by Indian Opponents

Christian Köster†
Dennemeyer & Associates SA, Poccistr 11, 80336 Munich, Germany

Received 31 January 2014, revised 19 March 2014

Third parties interested in challenging the validity of European patents can do so in opposition proceedings before the European Patent Office (EPO). Opposition proceedings before the EPO are less cost-intensive than national nullity actions against national parts of European patents. Opponents are not always successful, but there are typically good chances to have a weak patent revoked. Three examples of successful opposition proceedings are discussed in this paper. The examples refer to pharmaceutical patents in which Indian companies were involved as opponents. As seen in these case studies, there are various objections which might be raised against the validity of a European patent, all of which could ultimately lead to the revocation of the protective right under attack. European opposition procedures can therefore be a powerful tool to eliminate unjustified patent protection and to clear the way for business in Europe.

Keywords: European patents, opposition procedure, grounds for revocation

Where patent protection for a particular invention is desired in Europe, the European Patent Convention (EPC)[1] provides a centralized system of law which governs grant of patents effective for up to currently 38 contracting states.[2] Such patents are called European patents[3] and, once granted by the EPO, have the effect of a national patent granted by the contracting states, provided the validation requirements are met.[4] The territorial effect[5] of a granted European patent may therefore equal the effect of up to 38 national patents.[6] The EPC is a very useful system to obtain patent protection in all major European jurisdictions and almost all other European states. In 2013, the number of patent filings at the EPO reached a new maximum of more than 265,000 applications.[7]

As a general principle, where it is claimed that a protectable contribution to the state of the art has been made so that a patent should be issued, the public should also be able to determine whether the contribution in question deserves protection. In other words, there should be a possibility for third parties to either prevent the authorities to grant a patent in the first place, or to have a patent declared invalid after grant. This also holds true for the possibility to obtain patent protection in most European countries via the centralized system of the EPC. In this respect, the EPC basically opts for a post-grant review system, namely a post-grant opposition procedure.

In the EPC contracting states, national legal actions against the national part of a European patent are also generally available, often summarized as nullity actions. However, there are several aspects in favour of a European opposition procedure under the EPC as against bringing a nullity action into a national court. A European opposition procedure applies to the European patent in all contracting states in which that patent has effect.[8] If the opposition is successful, the European patent is then fully revoked. Compared to national actions, a central revocation of a granted patent is thus far more efficient for the opponent who will typically be interested in having the patent in suit declared invalid for more than one EPC contracting state. Further, in some jurisdictions a potential nullity claimant may be precluded from commencing a national nullity action because of an already pending European opposition procedure.[9]

Another significant factor is the cost for national nullity actions, on the one hand, and for a European opposition procedure, on the other. Typically, there is not only a single, but several national proceedings, so that the costs are easily multiplied. In contrast, there are fixed official fees for initiating the European opposition procedure and for filing an appeal. Moreover, oral hearings are seldom scheduled for more than one day, which reduces attorney's fees

†Email: ckoester@dennemeyer-law.com

when compared to several national nullity proceedings. Thus, eliminating a granted European patent by means of the central opposition procedure is generally much more cost effective than taking the route of national invalidity actions.

To summarize, European opposition procedures often have certain advantages over national nullity actions and deserve a closer look.

General Aspects of Oppositions before the EPO

When a European patent is granted, its grant is published in EPO's patent bulletin. Following the publication and hence post-grant, there is a period of nine months in which third parties can file a notice of opposition against the granted patent. For a potential future opponent, there is thus a timing issue. Once the nine month period has passed, oppositions cannot be validly lodged anymore.[10] Thereafter, the only way to attack a European patent's validity is by virtue of the afore-mentioned national nullity actions. Closely monitoring competitors' patent applications and the development of such application procedures is often necessary to not miss the grant of possibly business impeding patents and the opposition deadline.

Another important aspect is that, according to the relevant legal provisions of the EPC, 'any person' may lodge an opposition without e.g., requiring that the opposing party has a particular legal interest in the revocation of the opposed patent. It is not even required that the party interested in opposing a patent reveals its identity, as long as the acting opponent fulfills all the formal requirements for achieving the status of an opponent and does not abuse the opposition procedure under the EPC.[11] Therefore, it becomes irrelevant for the admissibility of an opposition whether the opponent acts on his behalf or on someone else's, so that oppositions filed by a 'straw man' can indeed be admissible.[12]

In the first instance, the opposition is heard by an Opposition Division, which is normally composed of three technically qualified members. Typically, they are recruited from the EPO's Examiner's Office because of their vast experience and training. In some particular cases, the Opposition Division may be enlarged by the addition of a legally qualified examiner. The procedure starts with a notice of opposition, and the patent proprietor is given the possibility to file his observations on the opposition in writing. These observations may include amendments of the granted patent in order to address objections raised by the opponent. There are no strict rules as to how the opposition procedure should then continue, and further written pleadings may be exchanged. Usually, at least one of the parties requests oral proceedings, so that all parties are at some point summoned to attend oral proceedings. In most cases, the Opposition Division renders a decision at the end of the oral proceedings. If the patent as granted or amended during the opposition procedure is considered to meet the requirements of the EPC, the patent is maintained. However, if at least one ground for opposition prejudices the maintenance of the European patent, the patent is revoked.

Whichever party is dissatisfied with the outcome of the first instance opposition procedure, may appeal the Opposition Division's decision. In the appeal procedure, the case is normally heard by a Board composed of two technically qualified members and one legally qualified member. In rare cases, the Board of Appeal sits in a composition of three technically and two legally qualified members, namely, where the Opposition Division was composed of four members, or when the Board of Appeal considers that the nature of the appeal so requires.

The appeal procedure is initiated when the appellant lodges a formal appeal and further files a statement on grounds of appeal. The respondent has at least one opportunity to reply to the appeal. Basically, the same legal rules as before the Opposition Division apply, but there is a specific set of rules of procedure for proceedings before the Boards of Appeal. There are instances where a Board of Appeal may refer one or more questions to the Enlarged Board of Appeal of the EPO, to ensure uniform application of the law, or if a point of law of fundamental importance arises. The procedure before the Enlarged Board of Appeal is a kind of intermediate procedure and may have an impact on the ultimate outcome of the appeal procedure. In any event, like in the first instance, the procedure typically ends with oral proceedings before the Board of Appeal and with a decision rendered at the end of this hearing.

In principle, the end of the appeal procedure terminates the opposition case before the EPO. However, a party which is adversely affected by the decision of the Board of Appeal may file a petition for review of the decision. Such a review of the decision is made by EPO's Enlarged Board of Appeal. The grounds for a successful petition for review are practically very narrow and limited, and successful cases have so far been rather the exception.

Accordingly, as a general rule, the opposition procedure is basically framed by the notice of opposition starting the procedure and by the terminating decision of either the Opposition Division - if not appealed - or the final decision of the Board of Appeal.

When starting the procedure and opposing a patent, the opponent can rely on various grounds for revocation, which are basically lack of novelty, lack of inventive step, insufficiency of disclosure and extension beyond the content of the application as originally filed. Opposition Divisions at the EPO rely on all these grounds whenever a patent is revoked in opposition procedures. The same holds true for the appeal instance: the Boards of Appeal also take into account all the possible reasons to revoke a patent before rendering a final decision. In fact, over the past years, unallowable extensions beyond the original disclosure have become a noteworthy issue.[13] While the patent proprietor has the opportunity to amend the granted claims in order to overcome the grounds of opposition, additional issues may arise in case of amendments, including lack of clarity[14] and inadmissible broadening of the scope of protection.[15] In order to illustrate actual examples of successful grounds of opposition, three case studies are presented below. They demonstrate that various attacks may finally lead to a revocation of a granted, but later opposed European patent.

Case Study I: The Issue of Novelty (the Merck Case)

In 2005, Merck & Co Inc, was granted a European patent (EP 0833643 B1) for the anhydrous form of the monosodium salt of an acidic organic compound known as 'alendronate' and for a pharmaceutical composition comprising this alendronate form. Alendronate is used as a drug in the treatment of osteoporosis and other bone diseases, and was undisputedly known as such prior to the patent. A notice of opposition against the patent was filed by Ranbaxy Laboratories Inc, where it was alleged that the patent as granted lacked novelty and furthermore lacked an inventive step. The patent proprietor decided to defend the patent in amended form, namely by specifying that the alendronate compound was present in crystalline form.

The Opposition Division held that the claimed crystalline substance as such indeed lacked novelty over a previous disclosure which Merck had made in an earlier European patent application procedure. On the other hand, the claimed pharmaceutical composition was considered novel because of the additional presence of a pharmaceutically acceptable carrier. Additionally, the previous critical disclosure was less relevant for the assessment of inventive step, and inventiveness was acknowledged by the Opposition Division because of a better solubility compared to what was considered the closest prior art, namely a trihydrated form of alendronate monosodium salt. The Opposition Division therefore maintained the granted patent in amended form, wherein the independent claim directed to the pharmaceutical composition read as follows:

> A pharmaceutical composition comprising a pharmaceutically effective amount of the anhydrous crystal form of 4-amino-1-hydroxy-butylidene-1,1-bisphosphonic acid monosodium salt in a pharmaceutically acceptable carrier.

The opponent was not satisfied with the outcome of the first instance of the opposition procedure and lodged an appeal against the decision of the Opposition Division. The competent Board of Appeal, to which the case was allocated, issued summons to attend oral proceedings together with a lengthy written communication setting out the Board's preliminary assessment of the opposition.

It turned out that the Board of Appeal was rather inclined to revoke the patent in its entirety. Contrary to the Opposition Division's assessment, claim 1 as cited above was considered not novel. This was because the claim was seen to relate to a pharmaceutical composition comprising a pharmaceutical effective amount of the crystalline anhydrous alendronate monosodium salt in a pharmaceutically acceptable carrier. According to the Board of Appeal, the claim encompassed compositions of the crystalline anhydrous alendronate monosodium salt in an aqueous carrier. In the Board's preliminary opinion, a pharmaceutical composition of the alendronate monosodium salt trihydrate in an aqueous carrier, which was known from the prior art, could not be distinguished from a pharmaceutical composition of the crystalline anhydrous alendronate monosodium salt in the same carrier. In this context, it was considered immaterial whether or not the alendronate form disclosed in the prior art was a crystal form. Additionally, it was opined by the Board that the expression 'pharmaceutical composition' is not a synonym for medicament, i.e., that it is not restricted to the final form to be administered to patients.

The claim construction used by the Board of Appeal inevitably led to a serious novelty objection. Further objections indicated that, even if novelty could be established, an inventive step would have most likely been denied in the end. The Board's preliminary view had a decisive impact, because the patent proprietor thereafter abandoned the patent by disapproving the text of any of the requests on file at that time. The procedure thus ended with a decision from the Board of Appeal by which the decision under appeal was set aside and the patent was revoked.[16]

This case demonstrates that, although the novelty analysis applied by the various bodies of the EPO is typically narrow, so that novelty is often achievable for an applicant or a patent proprietor; lack of novelty may well become an issue again in opposition procedures and may win the case for the opponent. As also seen in this case, the inventive step can be a significant hurdle as well.

Case Study II: Alternatives are Often Obvious (the Teva Case)

In the second case presented herein, the patent proprietor was Teva Pharmaceutical Industries Limited. The concerned patent (EP 1685126 B1) contained - in its granted form - 52 patent claims. The patent was in particular directed to the preparation of candesartan cilexetil which is a so-called prodrug, i.e. a precursor of a drug molecule which is released from the prodrug after administration to the treated individual. In the case of candesartan cilexetil, the actually active ingredient candesartan is released when the prodrug passes the mucous membrane of the small intestine. The released candesartan acts in the body as an antihypertensive, so that it is effective in treating high blood pressure. Antihypertensives are often blockbuster medicaments, as was the case for candesartan. Related patents are therefore frequently subject to litigation, and unsurprisingly Teva's patent was opposed. In fact, three different companies gave notices of opposition to the EPO, namely Ranbaxy Laboratories Limited, KRKA, d.d., Novo mesto and Cadila Healthcare Ltd.

During the oral proceedings before the Opposition Division, the proprietor defended the patent on the basis of a set of amended claims. These claims were categorized into three groups by the Opposition Division. The first group addressed a process for preparing cilexetil trityl candesartan starting from trityl candesartan, the second group was directed to a method of synthesizing cilexetil candesartan using cilexetil trityl candesartan as a starting material, and the third group was directed to another process of synthesizing cilexetil trityl candesartan from trityl candesartan.

All three opponents argued that the claimed processes lacked novelty and furthermore lacked inventive step. In the Opposition Division's decision, novelty was briefly discussed and a difference *vis-à-vis* the cited prior art documents was identified for each of the claimed processes. Consequently, novelty was acknowledged by the Opposition Division.

For the analysis of the requirement of an inventive step, the processes of the first and the third group were examined together. Compared to the prior art, which used dimethylformamide as a reaction solvent, the claimed processes differed in that the synthesis of the targeted cilexetil trityl candesartan was carried out in a solvent having a boiling point below 140°C or in acetonitrile. The Opposition Division analysed the experimental data provided in the patent and came to the conclusion that no advantage or technical effect as compared to prior art could be attributed to the use of a solvent according to the claimed processes.

Moreover, one of the prior art documents proposed other alternatives to dimethylformamide, including acetonitrile, acetone and ethyl methyl ketone having boiling points below 140°C. It was also held by the Opposition Division that the selection of an appropriate solvent for a specific reaction is within the usual routine work of the person skilled in the art. As a result, with regard to the first and third group of claims, the opposed patent was considered to provide nothing but a mere alternative to the preparation of cilexetil trityl candesartan, as known from the prior art. This alternative was assessed to be an obvious alternative, and an inventive step was consequently denied.

The processes of the second group of opposed claims involved a deprotection step of cilexetil trityl candesartan to cilexetil candesartan. In principle, such a process was known from the prior art. The Opposition Division however, identified one difference from the prior art, namely, the use of an organic acid or methanol without an acid, instead of hydrochloric acid in methanol, for removing the trityl protecting group. No technical effect was attributed to this difference by the Opposition Division. The proprietor's submission that the claimed process

provided cilexetil candesartan of higher purity was rejected because it was not substantiated, although the proprietor had in fact filed comparative data. The Opposition Division emphasized that comparative tests must meet certain criteria, and that there must be maximum similarity between the compared products or processes. This criterion was not met because of more than one differing feature, which made a meaningful comparison impossible, according to the Opposition Division.

The Opposition Division also pointed to additional cited prior art in order to demonstrate that organic acids had already been employed in the prior art for the same purpose as in the opposed patent, namely, for removing a trityl protecting group from biphenyl tetrazole compounds. Such tetrazole compounds are structurally similar to candesartan, and one prior art document disclosed that there is no limitation upon the nature of the acid, organic or inorganic, used in the removal of a tetrazolyl-protecting group. According to the prior art, the acids that were preferred were acetic acid, formic acid, trifluoroacetic acid or hydrochloric acid. It also described that the reaction could advantageously be effected in the presence of a solvent such as methanol.

Further prior art documents cited in support of the filed oppositions taught the removal of trityl protecting groups from structurally similar biphenyl tetrazole compounds in methanol/acetic acid, in methanol/tetrahydrofuran and in refluxing methanol. In view of this teaching found in various prior art documents, the Opposition Division concluded that it would be obvious to the person skilled in the art to apply the known technical concepts with corresponding effect to the deprotection of cilexetil trityl candesartan with an expectation of success. Therefore, also the second group of claims was found to lack an inventive step.

As a result of the opposition procedure in the first instance, the opposed patent was revoked for lack of inventive step. The proprietor did not appeal the negative decision, and the patent was indeed successfully opposed and revoked because no inventive contribution to the art was acknowledged.

Case Study III: Several Ways a Patent is Lost (the Sepracor Case)

In this case, a European patent (EP 0969836 B1) granted to Sepracor Inc covered lactose-free pharmaceutical compositions of descarboethoxyloratadine. The active ingredient, descarboethoxyloratadine, is the major metabolite of loratadine, which acts as an H-1 histamine receptor antagonist. The patent described that H-1 histamine receptors mediate the response antagonized by conventional antihistamines, and that loratadine was shown to be comparable in antihistaminic activity to terfenadine and astemizole, and on a milligram by milligram basis, four times more potent than terfenadine in the inhibition of allergic bronchospasm. It was also explained that descarboethoxyloratadine is favorable over loratadine because it is significantly less active in tumour promotion and simultaneously more potent.

Descarboethoxyloratadine as such was known and the patent sought protection for a pharmaceutical composition thereof. It was however, opposed by Lupin Limited, Nina Louise White[17] and Teva Pharmaceutical Industries. The opponents raised several objections: lack of novelty, lack of inventive step, and in addition insufficiency of disclosure and inadmissible extension beyond the content of the application as originally filed. The patent proprietor decided to defend the patent on the basis of a Main Request and three Auxiliary Requests. Auxiliary Requests are only examined in case a higher ranking request like a Main Request is found not allowable, and are examined in the order indicated by the requester. The Opposition Division of the EPO handling this case examined all requests submitted by the proprietor.

The independent claim of the Main Request contained the expression ‘free of reactive excipients’ which was taken from the description and introduced into the claim as granted. The amended subject matter was examined for all requirements of the EPC, including the requirement of clarity.[18] In this regard, the Opposition Division referred to the examples of the opposed patent which described compositions allegedly free of reactive excipients. However, the described compositions contained excipients like stearic acid, which, according to some prior art documents, qualified as ‘reactive excipients’. The Opposition Division was thus of the opinion that there was no clear definition in the patent of ‘reactive excipient’.

A reference to a pharmacopoeia indicated in the patent and the described possibility to use an appropriate assay to identify whether or not a given compound would fall within the definition of a reactive excipient was of no help to the proprietor. The Opposition Division argued that it would require undue experimentation to randomly screen undefined

compounds for the activity of interest. Additionally, it was held that there was also no unequivocal definition generally accepted in the art for the feature 'reactive excipient'. As a result, the Main Request was not allowed because it lacked clarity.

The first Auxiliary Request contained claims as granted which referred to the claimed composition as being 'lactose-free'. The application documents as originally filed referred to descarboethoxyloratadine compositions 'substantially free of reactive excipients, such as lactose or other mono- or di-saccharides'. The Opposition Division concluded from the original application documents that the disclosure was restricted to such compositions devoid of any reactive excipients, not only free of lactose. The examined claims however, did not exclude the presence of reactive excipients, other than lactose, in the composition, and were therefore seen as going beyond the content of the application as originally filed. Such an extension of the original disclosure is not admissible under the EPC, and the first Auxiliary Request was consequently not granted.

In the second Auxiliary Request, a functional definition was used by the proprietor to define the reactive excipients. According to the Opposition Division, the used definition combined two different aspects of the application such that the resulting combination lacked proper basis in the documents as originally filed. Moreover, it was ruled that the functional terms chosen to define the reactive excipients led to clarity issues. Due to these deficiencies, the Opposition Division did not admit the second Auxiliary Request into the proceedings.

The final and third Auxiliary Request claimed a pharmaceutical composition of descarboethoxy loratadine together with a pharmaceutically acceptable carrier. The composition was in particular defined by a certain particle size distribution of the active ingredient. The third Auxiliary Request was sufficiently disclosed, had fair support in the original application documents and was novel over the cited prior art. Thus, the decisive question was whether or not the inventive step requirement was satisfied.

Pharmaceutical compositions, namely tablets, comprising descarboethoxyloratadine with a pharmaceutically acceptable carrier were known from various prior art documents which were equally used by the Opposition Division as a starting point for the assessment of inventive step. The novelty-establishing difference was seen in the presence of large descarboethoxyloratadine particles. While the patent proprietor claimed that this feature led to an enhanced stability, the Opposition Division disagreed because the alleged stability had not been proven. In particular, the examples of the opposed patent did not, in the Opposition Division's opinion, support any stability effects which could have been attributed to the feature of a particular particle size. As an intermediate result, the technical problem solved by the pharmaceutical composition according to the third Auxiliary Request was seen in the provision of an alternative descarboethoxyloratadine composition.
The Opposition Division opined that the problem of finding an alternative descarboethoxyloratadine composition would have been solved by the ordinarily skilled person, by selecting the particle size in question. The reasoning was that this size was a commonly used particle size, not connected to any special credible effect and commonly used in tableting techniques. Therefore, an inventive step was denied and the third Auxiliary Request was rejected.

The unsuccessful patent proprietor lodged an appeal against the Opposition Division's decision, but later withdrew it. Accordingly, the decision became final and the opposed patent was finally revoked on the various grounds of opposition discussed above. As seen from this case, oppositions against European patents can be successful based on quite different objections against both, claims as granted and as defended in amended form.

Conclusion

The EPC provides a centralized procedure to obtain patents in all major countries in Europe. Correspondingly, it is also possible to oppose granted patents in a centralized procedure under the EPC. A successful opposition affects the patent as a whole, without having to go through national invalidation proceedings. Opposition proceedings before the EPO are therefore an interesting possibility for third parties to eliminate unjustified patent protection. Some Indian companies, in particular in the pharmaceutical sector, make use of this procedural option in order to safeguard their business interests in the form of expansion into the European market. Various case studies, three of which are summarized in this paper, teach us that several different objections may be raised by opponents in EPC opposition procedures, and that all of them may indeed be successful so that the business impeding patent is revoked.

References

1 Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.

2 All EU member states are contracting states of the EPC; but the EPC system covers other countries too e.g., Switzerland and Turkey.

3 Article 2(1) EPC; also referred to as 'EP patents'.

4 Article 2(2) EPC.

5 Article 3 EPC.

6 On 20 January 2013, two European Union Regulations entered into force which allow grant of European patents with unitary effect for participating member states. The Regulations require that a Unified Patent Court is established in Europe beforehand. On 19 February 2013, an Agreement on a Unified Patent Court was signed by 25 EPC member states. The Agreement is yet to be ratified in the participating member states. The ratification processes are on-going and expected to be time consuming.

7 Figure taken from the EPO's website, http://www.epo.org/news-issues/news/2014/20140116.html.

8 Article 99(2) EPC.

9 For example in Germany, see Section 81(2) of the German Patent Law. This section is also applicable to European patents granted with effect for Germany as ruled by the German Federal Supreme Court (BGH GRUR 2005, 967 – Strahlungssteuerung).

10 However, according to Article 105 EPC, a third party may intervene in opposition proceedings after the opposition period has expired, if the third party proves that proceedings for infringement of the same patent have been instituted against him, or following a request of the proprietor of the patent to cease alleged infringement, the third party has instituted proceedings for a ruling that he is not infringing the patent.

11 Decisions G 3/97 and G 4/97, OJ EPO 1999, 245, 270.

12 Case Law of the Boards of Appeal of the European Patent Office, Seventh Edition, September 2013, IV.D.2.1.3.

13 See for example, Köster C, Article 123(2) EPC, Recent Case Law and a Chessboard, *epi Information*, 3 (2012) 71-77.

14 Decision G 9/91, OJ EPO 1993, 408.

15 Article 123(3) EPC.

16 Decision T 625/08 (not published in the OJ EPO)

17 A professional representative, presumably acting as a straw man.

18 Lack of clarity as such is no ground for opposition under the EPC, but in this case the subject matter of the Main Request had been amended compared to the granted claims and was thus open to clarity objections.