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Patenting Biotechnological Inventions in Europe

Saša Bavec[1]* *and Peter Raspor*[2]

[1]LEK, Pharmaceutical and Chemical Company, d.d, Verovškova 57, SI-1526 Ljubljana, Slovenia

[2]Biotechnical Faculty, University of Ljubljana, Jamnikarjeva 101, SI-1000 Ljubljana, Slovenia

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Introduction

The patent system has been able to provide the protection for the achievements of different technologies and in that way it has supported further development and growth of the industry where those achievements were implemented. Modern technologies like information technology and biotechnology with genetic engineering that appeared in the 70s have overgrown the frames of the existing patent system because of their exponential development during the last thirty years. Industry that invests a huge amount of money in these technologies, especially in the field of biotechnology, where the results are very uncertain, has started to claim changes in the patent system.

The term biotechnology represents a huge and comprehensive field of science and its application. Genetic information and its expression are the most important and innovative part of current knowledge in biotechnology. Rapid development of biotechnology in the last years is based mainly on these two items. Modern biotechnology has broken many basic principles of patentability and in addition to the above, has set out many ethical and moral issues related to »the patenting of life«. There were several attempts, some of them also controversial, to shape an appropriate legal framework for the protection of biotechnological inventions, especially inventions in the domain of molecular biology. Different countries have generated different solutions which have resulted in the development of several different patent practices.

The purpose of this paper is to show the current approach of the European Patent Office (EPO) in regard to the prosecution of patent applications and to the patent granting in the field of biotechnology.

Biotechnological Patents at the EPO

The present centralized European system for granting patents originated in 1973 when the European Patent Convention (EPC) was adopted. The original version was partly changed and amended later but the basic principles have remained the same (the most recent changes were proposed at the conference in Munich, November 2000). Today, it is possible to get protection for an invention by a single European patent application filed at the EPO in 24 European countries-members of the EPC and in six so-called »extension countries« that have signed a special »extension agreement« (Table 1). The whole procedure for granting patents (from filing of a patent application to its examination and final grant of patent) is centralized and performed by the EPO. After the grant the »European patent« becomes a bundle of independent national patents, which are further in terms of validity, enforcement and interpretation of common rules of the EPC related to the determination of scope of granted protection subject to national legislation and legal practice.

According to the EPC novelty, the substantive requirements for patentability are inventive step and industrial applicability, as it is the case everywhere in the world. Discoveries and methods for treatment of human or animal body by surgery or therapy and diagnostic methods practiced on human or animal body are not regarded as patentable inventions. Inventions, the publication of which would be contrary to »ordre public« or morality, plant or animal varieties and essentially biological processes for the production of plants or animals are specifically excluded from patentability. The EPC requires that a European patent application discloses the inventions in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The subject matter for which the protection is sought should

* Corresponding author; Phone: +386 1 580 25 34; Fax: +386 1 568 35 26; E-mail: saso.bavec@lek.si

Table 1. List of the EPC member states and countries with »extension agreement«

EPC members				
Germany	Italy	Netherlands	Austria	Denmark
UK	France	Belgium	Portugal	Cyprus
Switzerland	Greece	Luxembourg	Ireland	Finland
Sweden	Spain	Liechtenstein	Monaco	Turkey
Slovakia	Czech R.	Bulgaria	Estonia	
Extension countries				
Slovenia	Romania	Latvia	Albania	Macedonia
Lithuania				

be determined by claims. They should be clear, concise and supported by the description.

Main Dilemmas Related to Patenting of Biotechnology Inventions

The basic requirements for patentability of biotechnological inventions are the same as for the inventions from the other technological fields, but in some cases the frames of the patent system are too narrow. Biotechnology has in some places »ruptured« the patent system which has struggled to adjust the application of the system to this new technology (*1*). Firstly, it is very difficult to present a biotechnological invention sufficiently only by description of its component parts as it can be done with most of other inventions (*i.e.* classic inventions in chemical and mechanical fields), but it should be defined by functional terms and sometimes even that is not enough. In these cases (*i.e.* new strains, improved strains and hybridoma cells), the deposit of biotechnological material is necessary. This feature has challenged the requirement of patent law for a description of an invention in a written form. Secondly, the traditional distinction made by patent law between a mere discovery and an invention has been challenged, because many of biotechnological inventions are naturally occurring matters like (micro-) organisms, as well as proteins, nucleic acids, polysaccharides *etc.*, which have already existed in nature for a long time, but they had not been isolated and specified before. Consequently, they can also be in a sense considered as discoveries. Thirdly, despite the fact that patent system has for a long time been formally connected with morality, it was very rarely considered that granting patents had something to do with it. Biotechnology has changed this view and several groups have started actions to ban »patenting of life«. This is a result of misunderstanding and misconception of the link between patents and morality issues. In the last few years the European patent system has become less limiting factor for the development of European biotechnological industry as it was case in the past, when as a consequence of existing patent system and undeveloped patent practice in the area of biotechnology, it could not grow as it could in optimal circumstances.

Non-Patentable Matter

According to Article 52(2)a EPC discoveries are not regarded as patentable inventions. The best approximation of the EPO standing regarding the line between discoveries and inventions is a mixture of two definitions. The first says that the line between discovery and invention represents a principle of »industrial applicability« and the other says that besides the discovery a human technical contribution and ingenuity are also necessary to make an invention patentable. The position of the EPO is best evident from the decision regarding »RELAXIN« where it stated the following: *To find a substance freely occurring in nature is mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if this substance can be properly characterized by its structure and it is new in the absolute sense of having no previously recognized existence, the substance per se may be patentable. The new Rules 23c(a) and 23e EPC have made this line between discovery and invention even more clear.*

Besides discoveries, the methods for treatment of human or animal body by surgery or therapy and diagnostic methods practiced on human or animal body are not regarded as patentable inventions. The main argument for that lies in the definition of »industrial applicability« in Article 52(4) EPC. According to the EPC, such inventions cannot be considered as susceptible to industrial application. A brief look into the EPO's practice shows that methods for treatments including surgical step are not patentable at all (Decisions of Technical Boards of Appeal, EPO T116/85 and T182/90). Diagnostic methods are patentable if they are used outside living human or animal body, *i.e.* body tissues or fluids, such as urine or blood (T385/86). These exclusions do not apply to products for use in any of these methods (Decisions of Enlarged Board of Appeal, EPO G5/83). For new products and products for which medical use is described for the first time it is also possible to obtain the so called »medical use claims«. »Second medical use« can be protected only by process claims as a process for the preparation of medicament.

Exceptions to Patentability

Inventions, the publication or exploitation of which would be contrary to »ordre public« or morality, are excluded from patentability (Article 53(a) EPC). The purpose of this exclusion is protection of public security and physical integrity of individuals as part of society. The standing of the EPO is that mere publication of biotechnological invention cannot be contrary to »ordre public«, but its exploitation is deemed to be if it is likely to breach public peace or social order or to seriously prejudice the environment (T356/93). The concept of morality is not determined so clearly, because it depends on the valid standards set by culture and society in which the system is implemented. For the purposes of the EPC the culture in question is the culture inherent in European society and civilization (T356/93). The question of morality in case of »patenting of life« (patents on transgenic animals and plants) still remains open. The position of the EPO regarding the publication is the same as in the case of »ordre public«, but the act of actual exploitation of particular invention is the one to which the moral test must be applied. The belief that

something should not be patented for ethical and moral reasons calls for an ethical judgment that is outside the patent law itself and therefore patent officials or judges can not be called upon to make it (*2*). The present standing of the EPO is evident from the case T19/90 (the case was appealed). The inventions like the Harvard onco--mouse shall not be excluded from patentability on the basis of immorality if the advantages outweigh the disadvantages they bring.

Plant and animal varieties as well as the essential biological processes for the production of plants and animals are explicitly excluded from patentability according to Article 53(b) EPC. The main reason for this exclusion of plants in the EPC is to avoid problems with double protection in the states where the protection of plant varieties through the system provided by the Union for the Protection of New Plant Varieties of Plants is also possible. The legal definition of term »plant varieties« is defined in the EPC Rule 23b (*3*). Additional clarification of this term was given by the latest decision of the Enlarged Board of Appeal from the end of 1999 (G1/98), where the claim in which specific plant varieties were not identified was not excluded from patentability, even though it might embrace plant varieties. We can hope that it would also be used as a guideline in further cases. Regarding patenting of animals the Board of Appeal stated that no general exclusion of the invention in the sphere of animate nature can be inferred from the EPC. The exceptions to patentability under Article 53(b) apply to certain categories of animals but not to animals as such (T19/90). The legal definition of the term »essential biological processes for the production of plants and animals« is given in Rule 23b (*4*). The approach of the EPO regarding the interpretation of this term is that the judgement should be done on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the results achieved (T320/87). In the decision in the case T356/93 EPO stating that a process for the production of plants comprising at least one essential technical step which cannot be carried out without human intervention and which has a decisive impact on the final result does not fall under the exclusions to patentability.

Novelty

One of the requirements of the EPC for inventions to be patentable is novelty. According to the definition in Article 54 EPC, an invention is novel if it does not form part of the state of the art. The state of the art comprises everything made available to the public by means of a written or oral description, by use, or in any other way before the date of filing the European patent application. Issues concerning the legal aspect of novelty related to so-called »grace period« and »voluntary disclosure« are not dealt with here. The date of filing of a patent within the meaning of Article 54 can also be a validly claimed priority date of an earlier other application. Sometimes it is difficult to decide if the invention is new, especially if it relates to naturally occurring substances. The position of the EPO is that the naturally occurring substance can be considered as novel if it is isolated for the first time and it has no previously recognized existence (»RELAXIN«). The same practice is applied in the case of microorganisms. A DNA sequence, although it is contained in the known gene library, is not considered as known until the specific hybridization probes necessary for its isolation and characterization are known (T301/87 and T412/93).

In case the invention is partially known from a prior art document, this prior art disclosure cannot defeat the novelty of the later patent application if it does not enable persons skilled in the art to apply it without undue burden (T81/87). In the case T576/91, where the prior art document had disclosed some basic principles for construction and preparation of plasmid, this written disclosure was not enabling. At the same time plasmid was not available to the public. The position the EPO took was that this prior art document did not contain an enabling disclosure for the preparation of the plasmid in question and therefore it could not be used to defeat novelty.

Inventive Step

An invention involves an inventive step if, regarding the state of the art, it is not obvious to a person skilled in the art. Other European patent applications that are not published before the filing date of European patent application are not considered to form the state of the art for the purpose of deciding whether there has been an inventive step or not (Article 56 EPC).

Biotechnological processes for the preparation of new products are very often analogues and known *per se*. Such processes involve, according to the EPO, an inventive step if the bio-process results in a new technical effect or in a new product that can be established by the unexpected properties of the end product (T119/82). New products similar to the already known products are considered to involve an inventive step if some surprising and unexpected effects in comparison with the structurally closest known product can be shown (T164/83). For the determination of an inventive step, in addition to the so-called »obvious to try with a reasonable expectation of success«, the EPO uses the approach which implies the ability of a person skilled in the art to reasonably predict, before the beginning of a research project, a successful conclusion of the said project within acceptable time limits (T296/93). If the approach of solving the problem is predictable, on the basis of the existing knowledge, but trying to put the predicted approach in practice, the person skilled in the art is faced with unexpected difficulties, then the invention shall be considered as involving an inventive step (T923/92). The invention shall not be considered *a priori* to involve an inventive step merely because of the fact that it consists only of already known elements (T60/89).

The EPO's definition of a person skilled in the art for the purpose of determination of inventive step is an average hypothetical person with general technical background and specific knowledge and expertise in the field of invention. In the case T60/89 the EPO defined a person skilled in the art as a researcher with the university degree or as a team of researchers working in laboratories practicing molecular genetics and genetic engineering techniques, at the time of the origin of the

invention. Later, it was followed by the definition, that from the person skilled in the art it was not expected to solve technical problems by performing scientific research in areas not yet explored (T500/91).

Industrial Applicability

To be patentable an invention shall be applicable in industry (Article 52(1) EPC), which means it can be made or used in any kind of industry, including agriculture (Article 57 EPC). The main purpose of this requirement is to exclude the patenting of ideas which evidently do not achieve the claimed ends, such as machines to produce perpetual motion. The second issue of this requirement is to prevent the patenting of things, processes and scientific information having no known practical application as a priority (*5*). For most of the biotechnological inventions, showing the industrial applicability is not a big issue. The problem arises in the case of DNA sequences and genes without known function. Until now, the EPO has not granted any patent for DNA sequences, fragments of genes or genes themselves without known function. According to the EPO these kinds of inventions are deemed not to be applicable in industry (*3*). According to Jaenichen and Wachenfield (*4*), the patenting of DNA sequences like ESTs (expressed sequence tags) and SNPs (single nucleotide polymorphisms) at the EPO will remain questionable until the EPO gives some final decisions on this question and design a case law that can be used in support of that kind of patent applications. At the moment, the EPO's position is that the mere possibility of making something in industry (especially in the case of ESTs) is not enough to substantiate the industrial applicability – there shall also be disclosed a way how to use an invention in any kind of industry.

Sufficiency of Disclosure

An invention must be disclosed in a patent application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC). Despite the practice in the field of chemistry that a broad claim must be supported by several examples to allow a person skilled in the art to carry out the invention within the whole range that is claimed, the EPO allowed very broad biotechnological patent claims even when they were supported only by one example of performing the invention (T292/85). As it is evident from the decisions of the EPO issued in 1991, the practice regarding the sufficiency of disclosure has changed. As stated in the EPO case no. T548/91, the decision whether only one example of performing the invention is sufficient should be decided in each individual case. The disclosure of one way of performing the invention is sufficient only if it allows the person skilled in the art to carry out the invention in the whole range that is claimed (T409/91). Similar position was taken by the EPO in the case T435/91 where it is stated that the disclosure is sufficient only if it allows the person skilled in the art to carry out the invention within the whole area that is claimed without doing additional experiments on the »inventive level«. The principles set out by the last two conventional chemical cases were also applied in a more recent decision in the case T292/85.

Claims (Clarity, Support by Description, Scope of Protection)

The matter for which the protection is sought shall be defined by claims. They shall be clear, concise and supported by the description (Article 84 EPC). The claims, because of their function to define the scope of protection, shall be clear to ensure the sufficient degree of legal certainty to third parties. In general, an invention shall be defined by technical features, in the case of biotechnological inventions functional terms are also allowed. It is important that the definitions in the description and claims are not contrary to each other. In the case T939/92, the EPO took the position that technical features described and defined in the description as key features shall be the same as those used for the definition of the invention in the claims.

The aspect concerned by requirements for sufficient disclosure and support of claims by the description is the same although they are directed to different parts of the patent application – to ensure that the patent monopoly should be justified by the actual technical contribution of the invention to the art (T409/91). To determine if the claims are sufficiently supported, the whole patent application including the description and drawings (T1055/92) should be considered. Very broad claims are not *a priori* considered as unacceptable despite the fact that the description does not contain sufficient information to assume that all claimed substances also have the technical effect that is claimed. In case that an inventive step is grounded by technical effect, the question of sufficient support can be solved within the scope of Article 56 EPC (T939/92).

The extent of protection conferred by a European patent or European patent application shall be determined by the terms of the claims. The description and drawings shall be used to interpret the claims (Article 69 EPC). For determination of the scope of protection, literal meaning of the wording used in claims should not be used, neither should it be interpreted that the claims serve only as a guideline. Actual protection may be extended from a consideration of the description and drawings by a person skilled in the art to which the patentee has contemplated. The claims shall be interpreted in the way to give a fair protection for the patentee and to ensure a reasonable degree of certainty for third parties (Protocol on the Interpretation of Article 69 of the Convention). The actual determination of protection conferred by a European patent, as already mentioned at the beginning, is the matter of national legislation and case law. At the moment there are two main principles how to interpret the claims: the »English« principle is more in favour of the interpretation of given protection where the claims determine the outer borders of the given protection and the »German« principle favours the use of claims only as a guideline what the protection was given for. By harmonization in Europe, the differences between those two extremes are becoming smaller, but unified interpretation of the scope of protection

Table 2. Overview of the EPC and Directive regulations related to biotechnological patents including some examples of the related EPO case law

	EPC	EPO case law	Directive	Impl. of Directive in EPC
Non patentable matters				
– discoveries	Art.52(2)a	RELAXIN	Art.3(2) and 5	Rule 23c(a), 23e
– treatment/diagnosis	Art.52(4)	T116/85, T182/90, T385/86		
Exceptions to patentability				
– »ordre public«	Art.53a, Rule 34	T356/93	Art.6 and 7	Rule 23d
– morality	Art.53a, Rule 34	T19/90	Art.6 and 7	Rule 23d
– plant/animal varieties	Art.53b	G1/98	Art.2(3) and 4	Rule 23b(4), 23c(b)
– essentially biological processes	Art.53b	T320/87, T356/93	Art.2(2) and 4	23b(5)
Novelty	Art.54	RELAXIN, T81/87, T301/87, T576/91, T412/93		
Inventive step	Art.56	T119/82, T164/83, T60/89, T500/91, T923/92, T296/93		
Industrial application	Art.52(1) and 57			
– ESTs/SNPs			Art.5	Rule 23e
Sufficiency of disclosure	Art.83, Rule 27a and Rule 28	T292/85, T435/91, T409/91, T548/91, T923/92, G 2/93		
Claims	Rule 29			
– clarity	Art.84	T860/93		
– support of claims by description	Art.84	T409/91, T1055/92		
– scope of claims	Art.64 and 69*		Art.8, 9, 10 and 11	
Def. of biological material	Rule 28(6)		Art.2(1)a	Rule 23b(3)
Def. of microbiological process	Rule 28a, Guidelines, C-IV, 3.5	T356/93	Art.2(1)b	Rule 23b(6)
Def. of plant variety		G1/98		Rule 23b(4)
Deposit of biological material	Rule 28 and 28a	T418/89, T223/92, T412/93	Art.13 and 14	

* – criteria for interpretation of Art.69 EPC are stipulated by »Protocol on the Interpretation of Art.69 EPC« which is an integral part of the EPC

will be possible only by establishing a single patent court in Europe.

Unsolved and Unclarified Issues

The EPC and the EPO case law slowly make the European system for granting patents more »user friendly« for applicants of patents on biotechnological inventions. The implementation of the European Directive on the Legal Protection of Biotechnological Inventions (Directive; 98/44/ECC) in the European patent law by means of amendments to the EPC Implementing Regulations on September 1, 1999 was another step to further elimination of white and gray areas in European patent law. As shown in Table 2, the largest part of the important patent issues is already covered either by the EPC, the EPO case law or by implementation of the Directive in the EPC.

The unsolved and unclarified issues that still remain are the questions of morality, ethics and what is contrary to »ordre public« in relation to patenting biotechnological inventions, questions on patentability of human genome, ESTs and SNPs and the question of determination of the scope of protection granted by the European patent.

Biotechnological inventions and activities that are deemed as immoral, unethical or contrary to »ordre public« shall be made illegal by proper law or regulation rather than by trying to control and limit them through the patent system. A patent office is not the place to determine these questions. As soon as the burden of making assessments on this topic is removed from the patent office, the cases like T356/93 and T19/90 will become history.

Patentability of human genome, ESTs and SNPs has become a hot topic in the last years especially after the announcement that the entire human genome is sequenced. The authors' opinion is that genomic DNA, ESTs and SNPs should be treated as any other chemical or biotechnological invention. As it is usual for pioneer work, the granted patent claim could be broad, but by determination of real technical contribution of the invention to the art, as it was done by the House of Lords in the UK in the case of Biogen v. Medeva and by compulsory licensing, the effective scope of protection could be effectively limited.

The differences in the interpretation of granted protection also present a problem in the EU due to still unharmonized national legislation and national case laws in different EU countries. Until this problem is solved, the single market in the EU, especially free

movement of goods, is questionable. The solution is easy, at least in theory – single Community patent (Green Paper COM (97) 314) instead of a bundle of national patents and single European patent court, which will make »European patent case law« unified instead of several different existing national practices at present. This idea is becoming more and more popular and we can only hope that it will soon become reality. If the EPO and the EPC are to be the core around which this unified system is built, then we may expect that the decisions of the Board of Appeal and the Enlarged Board of Appeal will form the core of the new pan-European patent case law. The issue of the single European patent and integrated judicial system regarding litigation involving European patents was also discussed at the Diplomatic Conference to revise the EPC held in Munich on 29 November, 2000.

Conclusion

The EPC enables inventors to receive efficient protection for their inventions in more than 25 European countries. In view of the above written facts, it can be concluded that Europe already has an efficient harmonized tool for granting patents for biotechnological inventions, despite the fact that some areas of uncertainty still exist. Too late adoption of the patent system for the development of modern biotechnology has once already put the EU biotechnological industry in less favorable position in comparison with its US counterpart. The adoption of the Directive has made European environment more biotechnologically-friendly. The patent system is not an obstacle for the development of modern biotechnology anymore, but it is an element of promotion of its development.

Patents and »Academic Research«

Academic researchers are usually afraid of patents and believe that patents mean limitation of research and free exchange of information. This perception is a result of scarce knowledge about the patents. Patents have dual nature. Their first purpose is to motivate inventors to undertake and investors to finance a research by giving them an opportunity to compensate their investments in long term high risk research. Their second purpose is to spread the information, promote technical development and make the access to the technical knowledge easier.

Use of patented invention for pure research purposes does not mean an infringement of a patent. Academic institution can use patented information without fear of patent infringement. Once the research work gets commercial attribute, then it is necessary to obtain permission (licence) of the patent holder to use the patented invention. Nowadays licensing has become usual practice, especially in the fast developing fields like information technology, biotechnology, electronics and pharmaceutical industry. For example, the universities in the USA have already used patents and licences for years as one of the important sources for financing their research activities.

»Break-through inventions and discoveries« are usually reserved for the »big ones« that possess the substantial financial and human resources necessary for such achievements. Industry is always looking for »break-through inventions and discoveries« since they have a potential to represent a break-through in the terms of making money as well. In later stages of a life cycle of such break-through inventions the industry focuses on things that were of »lesser importance« at the beginning, like cheaper and more economic production, new ways of usage of the products and improvements of the product to be more user friendly or of better quality. These things become especially important after the expiry of patent when generic copies of the product appear on the market.

An example of such »break-through products« is recombinant erythropoietin, which in terms of world wide sale represents more than 5 billion US dollars. The basic patent for recombinant erythropoietin will expire in most of the EU countries at the end of 2004 and several producers of generic pharmaceutical products are preparing to take their piece of erythropoietin cake. They are looking for the technologies for the production of recombinant erythropoietin. This creates demands for erythropoietin expression systems, for host cells capable of efficient erythropoietin expression and for fermentation technologies enabling efficient production of erythropoietin. The technologies for erythropoietin isolation and purification, analytical methods and erythropoietin pharmaceutical formulations are of their great interest as well. The institutions (universities and research institutes) that are able to serve such needs of generic pharmaceutical industry can get their piece of erythropoietin cake too. All the above mentioned processes and products can be patented if they satisfy the criteria of novelty, inventiveness and industrial applicability as discussed before in this article. On the other hand, the originator is still looking for the expansion of his market with new medical indications and at the same time is preparing himself for the generic competition he will have to face. The use of the product for new medical indication is patentable and can create a monopoly for additional twenty years on at least a part of erythropoietin market. The originator is interested in closing the door for generic competition as well. The frequently used strategy to stop the generic competition comprises of filing the patents on all possible technologies enabling production of recombinant erythropoietin and final dosage forms containing it.

The above stated example shows the existence of several possibilities for non-commercial institutions to take their piece of the erythropoietin market. The basic knowledge and human resources that universities and research institutes possess can be efficiently applied for creation of the above mentioned subjects that are of interest to the originator as well as generic industry. The demands for knowledge and qualified human resources exist on the market and it is up to universities and research institutes to decide where the existing knowledge, experiences and human resources can be most efficiently used for raising finances through work for industry.

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Decisions of European Patent Office and its Bodies

The aim of the citation of the decisions of the EPO is to show what was the position of the EPO on the issues discussed in the article. At the same time the cited decisions represent guidelines for the EPO's patent examiners and in many cases form basis for the decisions of national courts when deciding on patent issues, as well.

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