Patentability trends across EPO examining divisions and boards of appeal

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One of the main changes at the European Patent Office (EPO) under Benoît Battistelli's presidency was the early certainty initiative in respect of examination and opposition. The object of this programme was to eliminate the EPO's historical backlog of pending applications by the end of 2020 and to streamline the prosecution of European patents and oppositions.

The quantitative success of this project is reliably reflected in the statistics included in *Modernizing the EPO for excellence and sustainability – Achievements 2010-2018 EPO*.

In 2015, for the first time, the EPO completed more pending orders than it received. And in only three years, between 2015 and 2017, the stock at the EPO was reduced by 27%.

Has the early certainty initiative affected EPO granting procedure quality?

It cannot be ignored that this project has provoked some criticism. The situation gave rise to an open letter signed by prestigious European patent law firms, stating that, among other concerns, the increased average speed of the proceedings was deteriorating the quality of the searches and the examination procedure.

The new president of the EPO, António Campinos, also seems to be concerned about the decrease in the quality and has started a constructive dialogue with examiners, law firms and other players, with the aim of investigating criticisms and removing the causes behind the lower quality.

In fact, a possible decrease in the quality of the examination procedure, which as a result leads to an increase in productivity and closure of files, can only be materialised into a greater number of grants, given that the refusal of a patent application is normally more complex than its grant and usually requires an oral proceeding.

The figures seem to corroborate the hypothesis of greater leniency in the granting of patents by the EPO in recent years. For example, the number of filings has remained stable or undergone moderate growth, as shown in the graph (see Figure 1) included in the EPO Annual Report 2017.

However, the number of grants has risen sharply according to the same source (see Figure 2).

Unfortunately, the number of refusals has not been made public. Nevertheless, it can be assumed that, at least in these first years, the acceleration in the examination stage has resulted in a significantly higher ratio of grants with respect to refusals.

Are there other factors favouring the granting of patents?

In the past few years the EPO's approach with regard to certain aspects related to the analysis of inventive step could be considered especially beneficial for patentees, and one explanation for the high rate of grants in this office.

One of these aspects is the determination of the closest prior art in the problem-solution approach used by the EPO to assess the presence of an inventive step.

The Guidelines for Examination contemplate the application of the problem-solution approach based on different closest prior art documents. However, in many cases, a strict policy of applying the problem-solution approach taking a single closest prior art is followed, excluding alternative problem-solution approaches starting

from different documents. This policy makes it easier to defend the inventive step.

The amendments introduced in the latest version of the guidelines (November 2018) could reinforce this practice. One additional change is that applying the problem-solution approach from different starting points is required only if it has been proven that these documents are equally valid springboards. Another modification is that, particularly in opposition proceedings, the structure of the problem-solution approach is not that of a forum where the opponent can freely develop as many inventive step attacks as they wish in the hope that one of the said attacks has a chance of succeeding.

Moreover, the first generally accepted criterion for the selection of the closest prior art is that it should be directed to a similar purpose or effect as the invention, or at least belong to the same or a closely related technical field as the claimed invention. However, the use of the objective technical problem for the definition of the closest prior art is a contradiction in itself when applying the problem-solution approach given that, in the sequence of steps of this approach, the closest prior art must be established before defining the objective technical problem. The usual EPO practice to determine the closest prior art often implies an *ex post facto* analysis of the documents of the state of the art.

Another aspect is the widespread practice in the pharmaceutical field of almost uncritically accepting post-filed evidence that leads to the granting of patents for inventions that were mere speculations at the time of filing. Although

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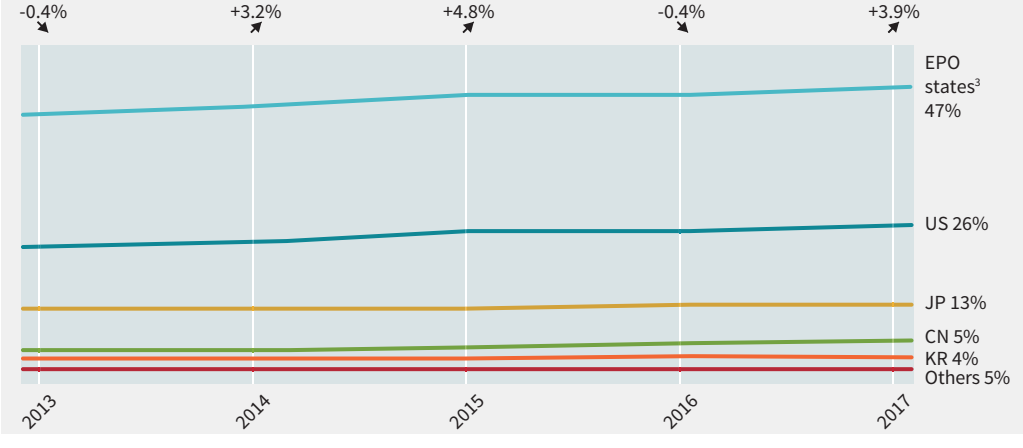
Since its establishment in 2015, Mr Zea has been CEO of ZBM Business Connect, a sister company of ZBM Patents & Trademarks assisting private companies and public research institutions with their technology transfer activities.

FIGURE 1. EPO Annual Report 2017



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Montserrat Jané has a strong background in organic chemistry, having been the head of research and development in a pharmaceutical company for 10 years. In that position she was also responsible for the company's patent issues. In 2002 she took up the patent profession full time at the Patent Centre of the University of Barcelona. Ms Jané joined ZBM Patents & Trademarks in 2004 and became a partner in 2005. She has extensive experience in searching, patent drafting and prosecution, opposition and appeal before the European Patent Office, and in preparing risk of infringement and validity opinions, especially in the fields of organic chemistry and pharmacy. She passed the European Qualifying Examination in 2008, and obtained the European Patent Litigation Certificate in 2015.

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After more than three years as a researcher in the medicinal chemistry laboratory of a multinational pharmaceutical company in Germany, Noemí Daviu returned to Barcelona in 2002 to join the patent profession. She worked in the patent departments of two outstanding Spanish pharmaceutical companies, and in 2007 she joined ZBM. Her job involves the drafting and prosecution of patents, as well as preparing patentability and infringement opinions. Ms Daviu passed the European Qualifying Examination in 2009 and became a partner with ZBM in 2010. In 2015 she obtained the European Patent Litigation Certificate, giving her the right to represent clients before the Unified Patent Court.

this fact may seem a specific characteristic of a particular sector, its importance should not be neglected. Moreover, bearing in mind how different technological sectors use the patent system, it is possible that in practice the pharmacy and biomedical sciences sectors are those that are more affected by examination, opposition and appeal at the EPO.

Which industry is most affected by the high granting rate?

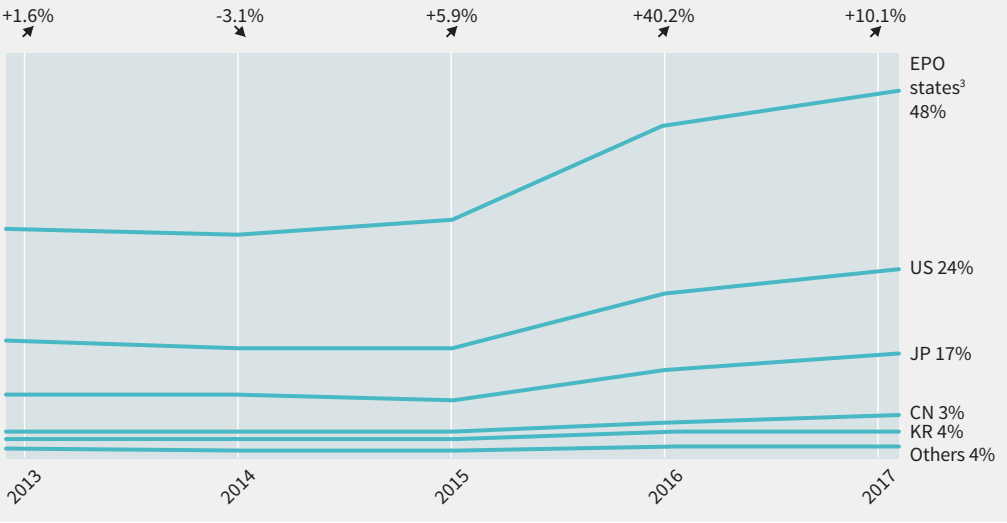
While at the EPO the top 10 applicants are IT, communication and electronic companies (this number goes beyond the top 50 in the United States), when the focus is placed on disputes the situation changes radically. The patents related to pharmacy and biomedical sciences are, by far, the ones that give rise to a greater number of oppositions at the EPO (see Table 1).

Thus, it seems reasonable to conclude that the evolution of the EPO in recent years, at least in the examining and opposition divisions, towards greater permissiveness when granting and maintaining patents in unamended or amended form, could have fostered oppositions, appeals and litigation, especially in the pharmaceutical field.

What is the situation in the United States?

Historically, similar circumstances could have occurred in the United States before the *KSR Int'l Co v Teleflex Inc* decision in 2007. Over many years, the United States Patent and Trademark Office (USPTO) was more lenient in granting

FIGURE 2. EPO Annual Report 2017



patents than the EPO and the Japanese Patent Office. Some authors (Cecil D Quillen Jr and Ogden H Webster, *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office – Updated*, The Federal Circuit Bar Journal, Volume 15, No 4, 2006, pages 635 to 677), correcting the data for continuation applications, estimate the grant rate of the USPTO was over 80% in the years preceding *KSR*, and over 90% taking into account continuations and continuations-in-part.

Within this framework the corrective factor of the US situation was the Supreme Court. This court has made a number of decisions since 2002 (*Festo Corp v Shoketsu Kinzoku Kogyo Kiab Co* (2002); *KSR, Bilski v Kappos* (2010); *Mayo Collaborative Servs v Prometheus Labs Inc* (2012); *Association for Molecular Pathology v Myriad Genet* (2013); and *Alice Corp v CLS Bank Int'l* (2014)) that have drastically reduced the strength of patents in the United States (Ali Mojibi, *An Empirical Study of the Effect of KSR v. Teleflex on the Federal Circuit's Patent Validity Jurisprudence*, Albany Law Journal of Science and Technology, Volume 20, No 3, 2010, pages 559 to 596). Unfortunately, in some cases this has led to a clearly unsatisfactory situation to adequately protect the interests of patentees and could remove the incentive to innovate. Among these decisions, *KSR* should be highlighted because it illustrates some of the possible problems that are currently occurring in the analysis of the inventive step in the EPO. This decision brought about a change in the way obviousness is assessed by implementing a broader and more flexible test that makes non-obviousness more difficult to prove. The Supreme Court held that not only the problem addressed by the patent but also any need or problem known in the field can provide a reason for combining prior art elements and, therefore, a skilled person attempting to solve a problem will not look only at those prior art elements designed to solve the same problem. In a nutshell, in *KSR*, the Supreme Court decided that rigidly applied standards for a determination of obviousness were inappropriate.

Changes imposed by the Supreme Court to reduce the strength of patents could explain the pharmaceutical industry's concern regarding the Unified Patent Court (UPC) in Europe, as evidenced by its initial position clearly in favour of the opt-out (ie, electing national courts for patent litigation instead of the UPC). This would also clearly explain the great reluctance to leave in the hands of the European Court of Justice (ECJ) the final decision on issues of validity and patent infringement, and the juggling that has been done to avoid creating the UPC as a an EU instrument to escape ECJ control.

Have corrections been made in Europe?

There are still no bodies in Europe that could drastically change EPO policy, since the UPC is not operational and the ECJ has no jurisdiction over patent issues. However, in the past two years it does seem that some differing viewpoints have emerged with respect to current EPO policy.

On the one hand, some boards of appeal decisions have referred to the problem and attempted to redirect it. Thus, for example, the current application of the problem-solution approach is being questioned internally, similarly to US Supreme Court criticism of the obviousness analysis in *KSR*.

According to Decision T2057/12 (9 May 2018), the jurisprudence of the boards of appeal has put significant emphasis on sharing a common purpose or aiming at the same object and on the similarity of the technical problem to be solved by the item of prior art to be selected as the closest prior art. The decision stated that these approaches limit the extent of the prior art to be considered when searching for the closest prior art and that it is questionable whether they are in agreement with an analysis of inventive step, which should be objective and consider all realistic circumstances which would lead to the claimed subject matter.

The board of appeal in T2057/12 also agreed with the findings of Decision T855/15 (10 January 2018), in particular that it cannot be excluded beforehand that real-world circumstances would have led a skilled person in a certain technical field to have given attention or even used an item of prior art from a completely different technical field. In T855/15, the board

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of appeal stated that the remoteness of a piece of prior art from the claimed invention does not, in itself, rule out an assessment of inventive step in view of that prior art.

On the other hand, in two recent decisions relating to late-filed evidence, the boards of appeal have raised the plausibility threshold to be met to accept the filing of post-filed evidence to defend patentability.

In the first case (T488/16, 1 February 2017), post-filed evidence confirming the activity of the drug dasatinib was used to defend the inventive step of the product claim. The board of appeal took the view that post-filed evidence could not be taken into account when assessing inventive step because it was not plausible to assume that at the filing date the invention solved the underlying problem.

In the second case (T950/13, 3 February 2017), also related to dasatinib, post-filed evidence was used to support the product's claimed therapeutic indications. The board again took the view that when there are substantiated doubts that the concept is credible, plausible or can be put into practice with the data present in the application as filed, post-filed evidence

TABLE 1. Patents related to pharmacy and biomedical sciences give rise to a greater number of oppositions at the EPO

Number of opposed patents	IPC class	Technological area
288	A61K	Pharmaceuticals, medical, dental and toiletries products
98	A61F	Prostheses, stents and other medical devices
70	C12N	Microorganisms or enzymes
68	A23L	Foods and non-alcoholic beverages
68	B65D	Containers
58	C08L	Macromolecular compounds compositions
57	F03D	Wind motors
53	B29C	Shaping or joining of plastics
49	C07C	Organic compounds (acyclic or carbocyclic)
48	C11D	Detergents and soaps

cannot be taken into account for acknowledging sufficiency of disclosure.

Not only are some boards of appeal beginning to move away from the previous permissive and unrealistic practices of the EPO on issues such as the limitation to certain closest prior art, but national courts are also taking a more pragmatic approach to inventive step.

Thus, the decision of the Barcelona Commercial Court No 4, 77/2018 (3 February 2018), established that in the selection of the closest prior art, any prior art that is cited against the validity of the patent must be taken into account.

The same line has been followed in the order of the Barcelona Court of Appeal 159/2017 (27 December 2017), which based the assessment of inventive step on the particular prior art document chosen as the closest prior art by the party challenging its validity.

Are the boards of appeal sufficiently independent of the EPO to lead a change?

The boards of appeal, although integrated within the organisational structure of the EPO, are independent in their decisions and are bound only by the European Patent Convention (EPC).

This independence has recently been revealed in relation to Decisions G2/12 and G2/13 of the Enlarged Board of Appeal of the EPO (*Tomatoes II* and *Broccoli II*), which allowed the protection of plants *per se*, even though they had been obtained by essentially biological methods.

Thus, after a subsequent notice of the European Commission on 3 November 2016, stating that the intention of EU Directive 98/44 was that such plants were not patentable, the EPO changed Rules 27 and 28 of the EPC to exclude them from patentability.

However, despite these EPO actions, Technical Board of Appeal 3304 recently held that Decisions G2/12 and G2/13 were correct in citing Article 164(2) of the EPC, according to which the provisions of the convention prevail in case of conflict with the implementing regulations.

Comment

During Battistelli's presidency the EPO showed greater permissiveness when granting or maintaining patents. In the absence of a European court that could change the situation in Europe, the EPO boards of appeal could facilitate a change in current EPO practice by raising the bar on the inventive step for European patents, just like in the United States when the Supreme Court raised the bar of obviousness.

The national courts could also contribute by using more realistic ways of assessing the validity of patents. **iam**

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