Validez de una patente: evaluación de la suficiencia de la descripción y la actividad inventiva

Lunes de Patentes

Madrid, 19 de noviembre de 2018

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CEO de ZBM Business Connect

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Profesor del Centre de Patents de la UB

¿El criterio sobre materia patentable y la calidad de las búsquedas y examen en la EPO son adecuados actualmente?

¿Son fuertes las patentes concedidas por la EPO?

¿Y las que superan una oposición e incluso un recurso?

El Tribunal Supremo ha puesto coto ¡y algo más! al sistema de patentes USA

WE DON'T LIKE THESE PATENTS

Jurisprudencia USA

- La jurisprudencia de los últimos años de Tribunal Supremo estadounidense claramente ha limitado los derechos de los titulares de patentes
  - Festo Corp v. Shoketsu Kinzoku Kogyo Kiab. Co (2002)

    Reforzamiento del *History Estoppel* como argumento de no infracción
  - KSR Int'l Co v. Teleflex Inc (2007)

    Criterios más estrictos para cumplir con el requisito de actividad inventiva

Jurisprudencia USA

- Bilski v. Kappos (2010)
  - No patentabilidad de ideas abstractas (limitación de las patentes relativas a los *business methods*)
- Mayo Collaborative Servs v. Prometheus Labs Inc (2012)
  - No patentabilidad de fenómenos naturales (afecta muy especialmente a los métodos de diagnóstico)
- Association for Molecular Pathology v. Myriad Genet. (2013)
  - No patentabilidad de genes (decisión extrapolada a todo tipo de productos naturales)
- Alice Corp v. CLS Bank Int'l (2014)
  - No patentabilidad de ideas abstractas

La EPO de Battistelli nadaba en otra dirección

Minutes of meeting of epi Biotech Committee with EPO Directors on 12 October 2015

3. Myriad in the US

It was noted that there has been a recent Australian decision on the Myriad case too. The EPC and the EU Biotech Directive are very clear about the patentability of human genes and there are numerous decisions from the technical Boards confirming and interpreting both. The EPO does not expect the problems the US and Australia are experiencing.

EPO claramente favorece las expectativas de los solicitantes

- G2/12 y G2/13 ("Tomatoes II" y "Broccoli II"), 25.03.2015, permiten la protección de los vegetales *per se* aunque se hayan obtenido por métodos esencialmente biológicos

La Comisión Europea presionó a la EPO para que cambiar su política

- El 03.11.2016 la Comisión hace un comunicado en el que indica que la intención de la directiva 98/44/EC era no ofrecer protección a estos productos

- En diciembre la EPO comunica que detiene todos los procedimientos en curso en relación con estas invenciones hasta clarificar el tema.
- EL 01.07.2017 cambiaron las Reglas 27 y 28 del CPE y estos productos se excluyeron de patentabilidad

Oposiciones / Recursos 2017 EPO

First-instance outcomes of opposition proceedings		
Patent maintained as granted (opposition rejected)	1262	31%
Patent maintained in amended form	1710	42%
Patent revoked	1099	27%

Final outcomes of opposition proceedings		
Patent maintained as granted (opposition rejected)	704	24%
Patent maintained in amended form	1121	39%
Patent revoked	1056	37%

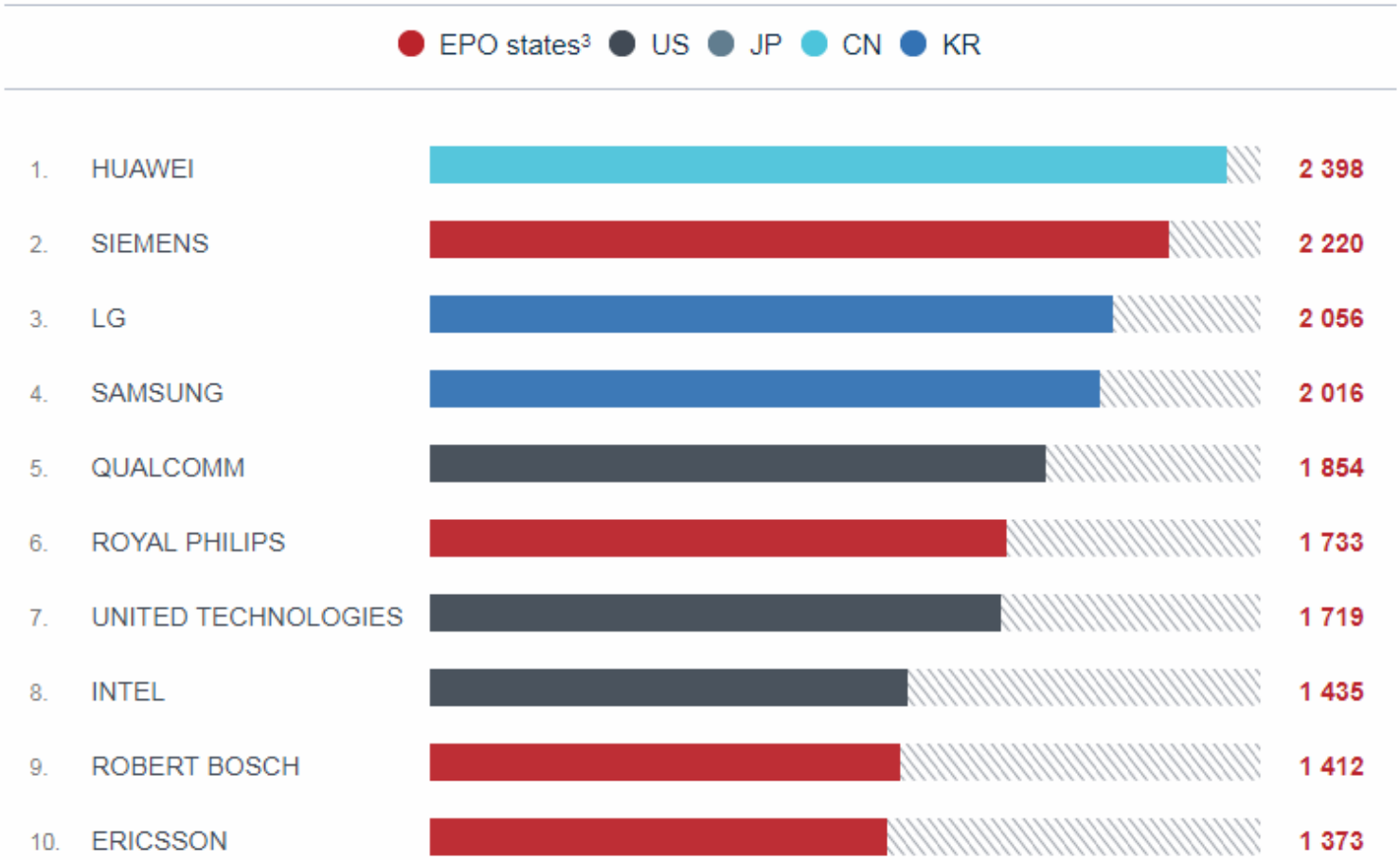
www.haseltinelake.com/media/1023436/haseltine_lake_oppositions_newsletter_july_2018.pdf

Los BoAs tienen un sesgo pro-titular

T2057/12 de 09.05.2018

3.2.2 …The jurisprudence of the Boards of Appeal puts also much emphasis on the similarity of the technical problem to be solved by the item of prior art to be selected... These approaches have in common to limit the extent of the prior art to be considered when searching for the closest prior art. **It is, however, questionable whether they are in agreement with an analysis of inventive step which should be objective and should hence take into account all realistic circumstances which would lead to the claimed subject-matter**…

Top solicitantes 2017



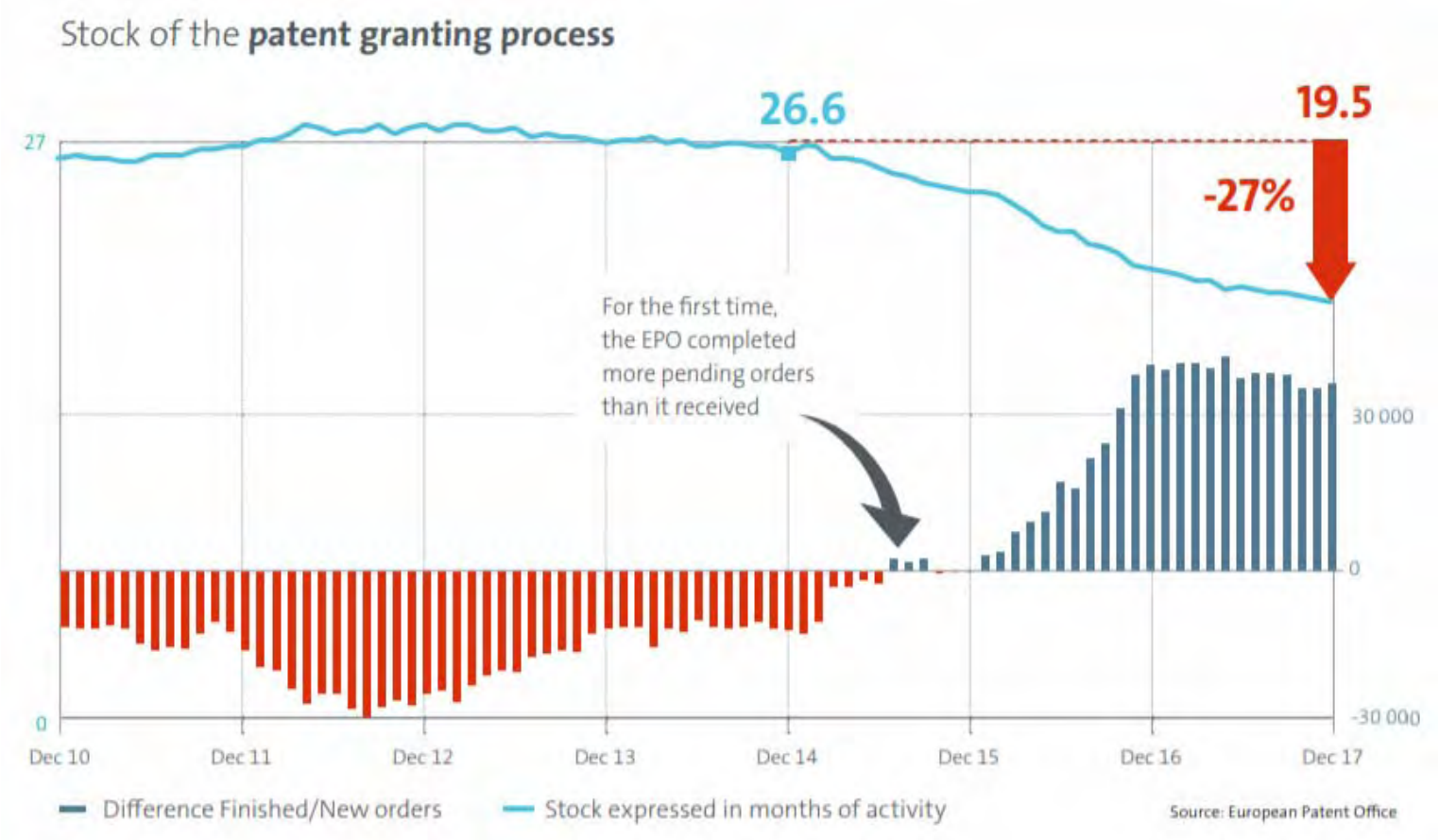
EPO Annual Report 2017

Oposiciones 2017 EPO – Áreas técnicas

Lead IPC subclass	No of patents	
A61K	288	Medical, dental, or toilet preparations
A61F	98	Stents, implants, prostheses etc.
C12N	70	Microorganisms or Enzymes;
A23L	68	Foodstuffs
B65D	68	Containers for storage or transport of articles
C08L	58	Compositions of macromolecular compounds
F03D	57	Wind motors
B29C	53	Shaping or joining of plastics
C07C	49	Acyclic or carbocyclic compounds
C11D	48	Detergent compositions

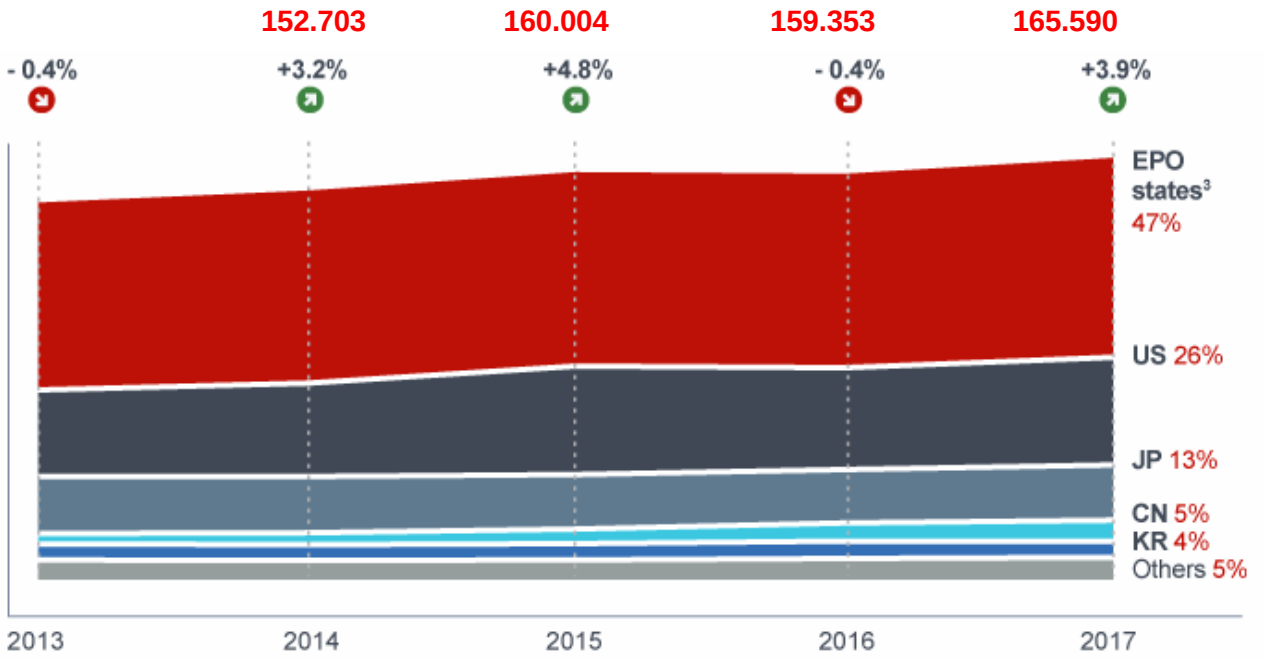
www.haseltinelake.com/media/1023436/haseltine_lake_oppositions_newsletter_july_2018.pdf

Y la EPO decidió incrementar la productividad



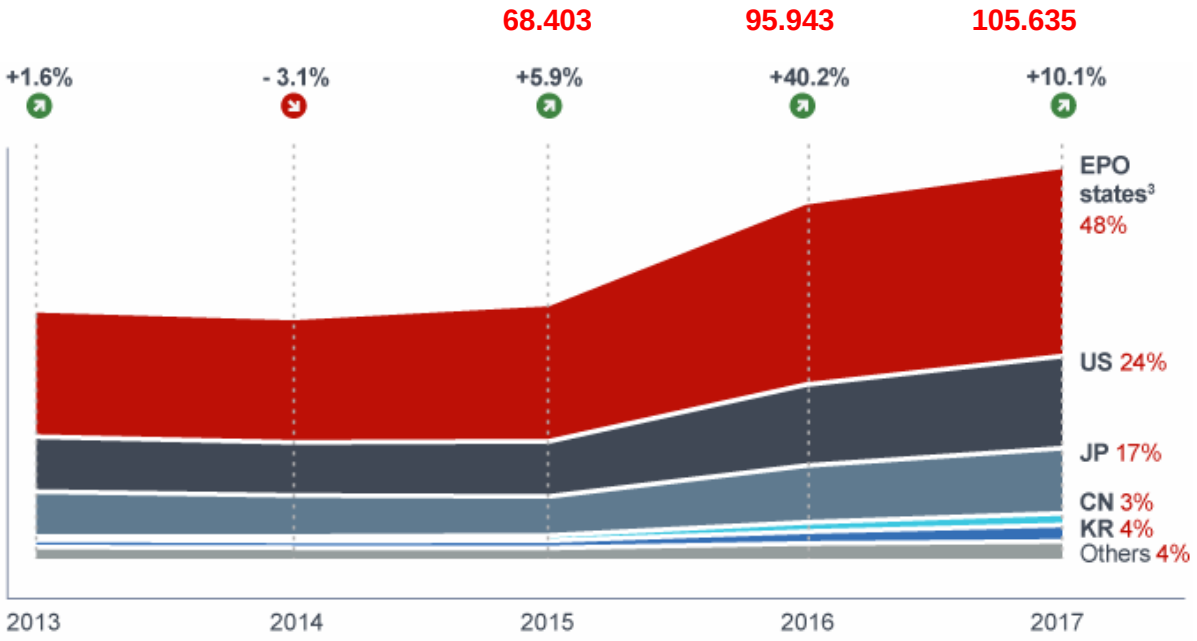
Modernising the EPO for excellence and sustainability – Achievements 2010-2018 EPO

Solicitudes EPO



EPO Annual Report 2017

Concesiones EPO



EPO Annual Report 2017

Disminución de la calidad en la EPO

Kluwer Patent Blog

EPO, EUROPEAN UNION, GERMANY

Leading German patent law firms criticize European Patent Office

Kluwer Patent blogger / June 14, 2018 / 38 Comments

Four leading patent law firms in Germany – Grünecker, Hoffmann Eitle, Maiwald and Vossius & Partner – have published an open letter expressing 'great concern' about the developments at the European Patent Office, particularly 'the modifications to the incentive systems for the examination of patent applications'.

Open Letter: Quality of Examination Proceedings at the EPO

Dear President Battistelli, Dear Dr. Ernst, Dear Mr. Morey, Dear Mr. Campinos,

Each year our law firms file more than 9500 patent applications with the EPO.

For several years now we have followed with great concern the developments at the European Patent Office, in particular the modifications to the incentive systems for the examination of patent applications. The incentive systems and internal directives appear to be increasingly directed towards ***rewarding or even requesting rapid "termination" of proceedings*** *and a correspondingly higher productivity. This has resulted in penalization of detailed and thorough assessment of cases.*

While we do appreciate the increased average speed of the proceedings, such an overreaching desire for high productivity has led to the following, specific problems regarding the examination of patents:

a) When the aim is to terminate proceedings as quickly as possible within specific allowed times, the quality of the search and examination of applications must suffer.

b) The fees for search and examination, which are rather high when compared internationally, can only be justified by giving the examiners sufficient time for an indepth assessment of each single application.

c) Patents that have been examined less thoroughly tend to have an erroneous scope of protection. This distorts and hinders economic competition within the EPC Member States.

d) Proprietors of inadequately examined patents are exposed to an increased risk of their patents not being able to be successfully asserted against competitors in their full scope.

e) If the users of the European system gain the impression that granted EP patents cannot be relied upon anymore due to insufficient search and examination, the users may increasingly be discouraged from filing European patents. This might unhinge the entire patent system.

f) The core task of the EPO is the examination and grant of European patents. This is an important public task, where the EPO needs to balance the interests of the public against the interests of patent applicants. The official fees are supposed to self-fund the EPO. However, in contrast to an industrial company, we cannot see why the profit of the EPO needs to be increased beyond the level of self-funding. From our perspective, the high surplus is rather an indication that the fees are too high and that a further, problematic increase of productivity is not appropriate.

We have observed that our perception of endangered quality of the examination of European patent applications is shared by a large number of patent examiners. As you know, a petition was recently published in which more than 900 examiners at the European Patent Office revealed that they are prevented by the internal directives from a thorough, complete search and examination.

In view of this background, we urgently suggest setting up new incentive systems for examining European patents so that the high-quality of searches and examinations for which the European Patent Office used to be known will be guaranteed again.

La presunción de validez de las patentes EP concedidas, incluso si han superado una oposición y recurso, se ve afectada por la política de la EPO

...Aunque hay indicios de cambio en ciertos BoAs para valorar de manera más razonable la validez de las patentes... e incluso de cierto cambio en la orientación hacia una mayor calidad de la propia EPO tras la entrada de Campinos (se ha anunciado una reducción en los objetivos de unos 430.000 “productos” en 2018 a unos 400.000 en 2019)

Pinceladas sobre requisitos de patentabilidad

La reivindicación es la unidad de protección

Article 84 – Claims

The claims shall define the **matter** for which protection is sought. They shall be clear and concise and be supported by the description.

La validez/nulidad se juzga a partir de toda la materia reivindicada

Article 100 - Grounds for opposition

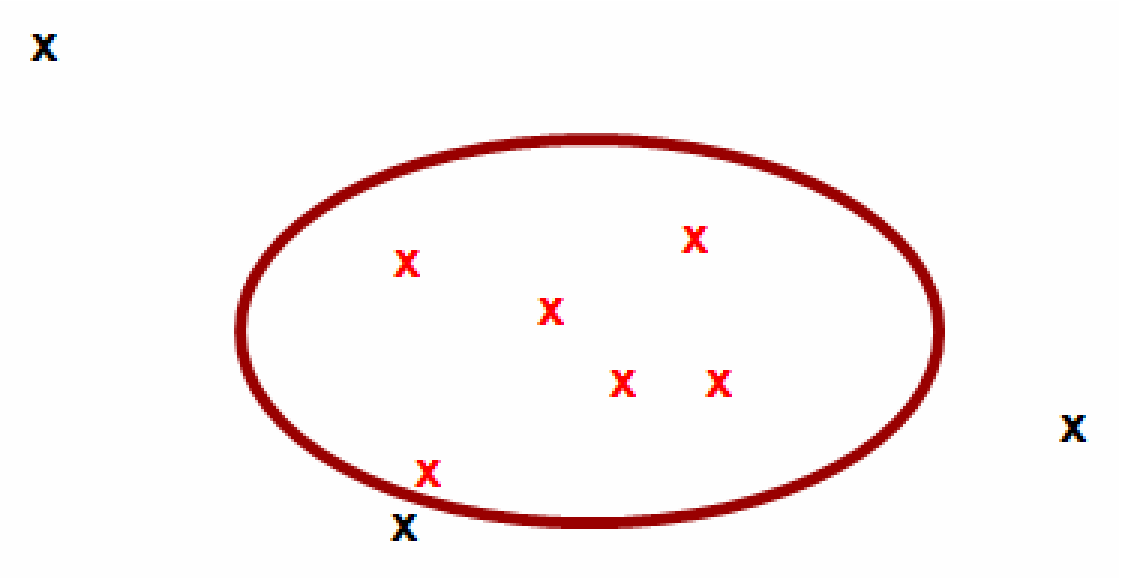
Opposition may only be filed on the grounds that:

(a) the subject-matter of the European patent is not patentable under Articles 52 to 57;

(b) the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

(c) the subject-matter of the European patent extends beyond the content of the application as filed, or, if the patent was granted on a divisional application or on a new application filed under Article 61, beyond the content of the earlier application as filed.

Es viable usar diferentes argumentos de nulidad frente a diferentes realizaciones de una reivindicación

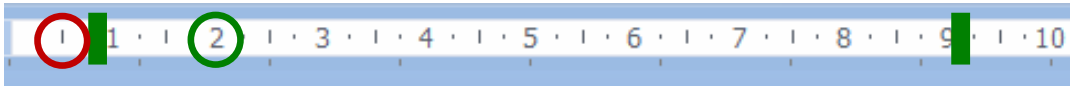


Ejemplo - Nueva aleación ¿mejorada?

Estado de la técnica: 8% A – 92% B

1. Aleación que comprende un 10-90% de un metal A y un 90-10% metal B

Ejemplo 20% A – 80% B

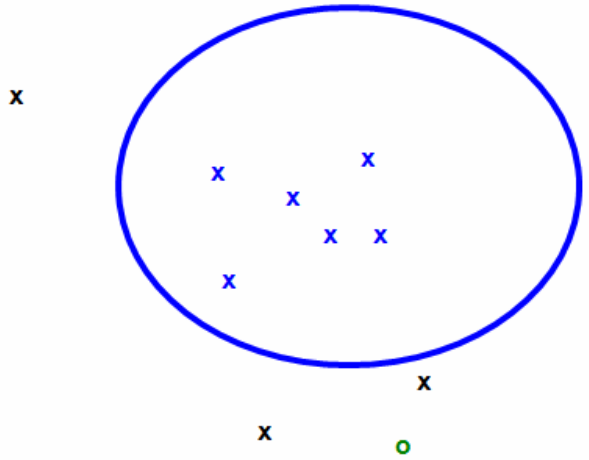


Producto comercial 35% A – 65% B

Es viable y lógico en centrar el análisis de actividad inventiva y suficiencia de la descripción en realizaciones diferentes y que no coincidan con los ejemplos ni el posible producto comercial.

Diferentes análisis diferentes resultados

- ¿Puede ser una reivindicación obvia y estar insuficientemente descrita al mismo tiempo?
- ¿Puede una realización ser obvia (no act. Inventiva) respecto a una patente y, en cambio, no ser equivalente en el análisis de infracción de esa misma patente?



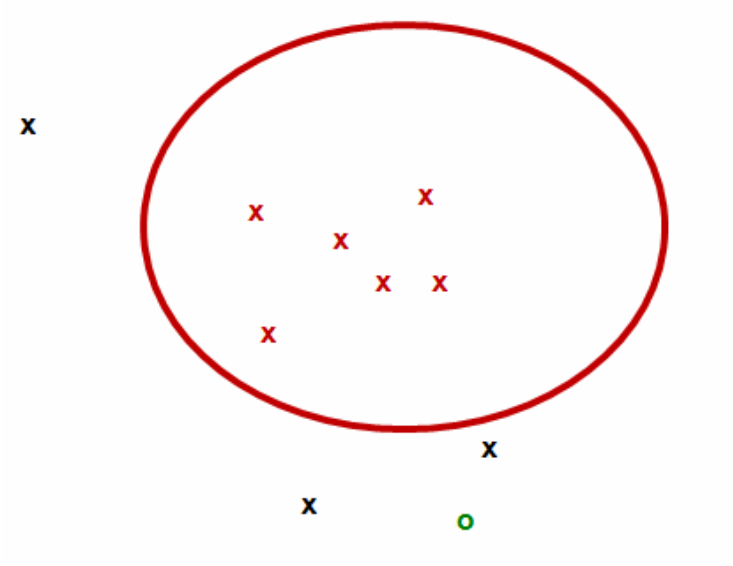
Cronología

Negro: Realizaciones del estado de la técnica

Azul: Patente y sus ejemplos

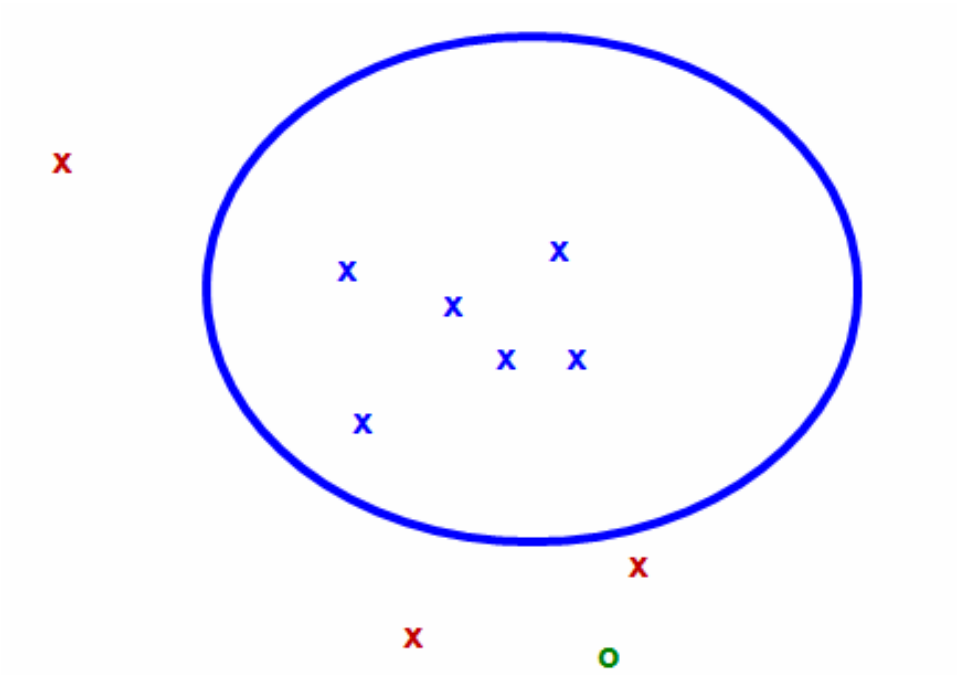
Verde: Realización posterior (posible solicitud de patente)

Suficiencia de la descripción de la patente



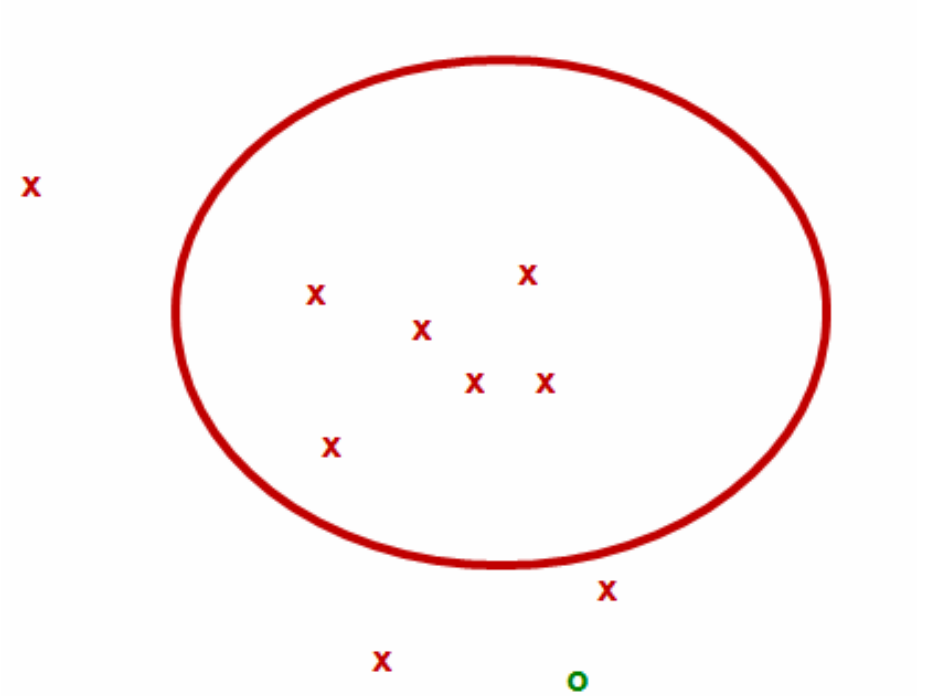
Rojo muestra documentación relevante para el análisis

Actividad inventiva de la patente



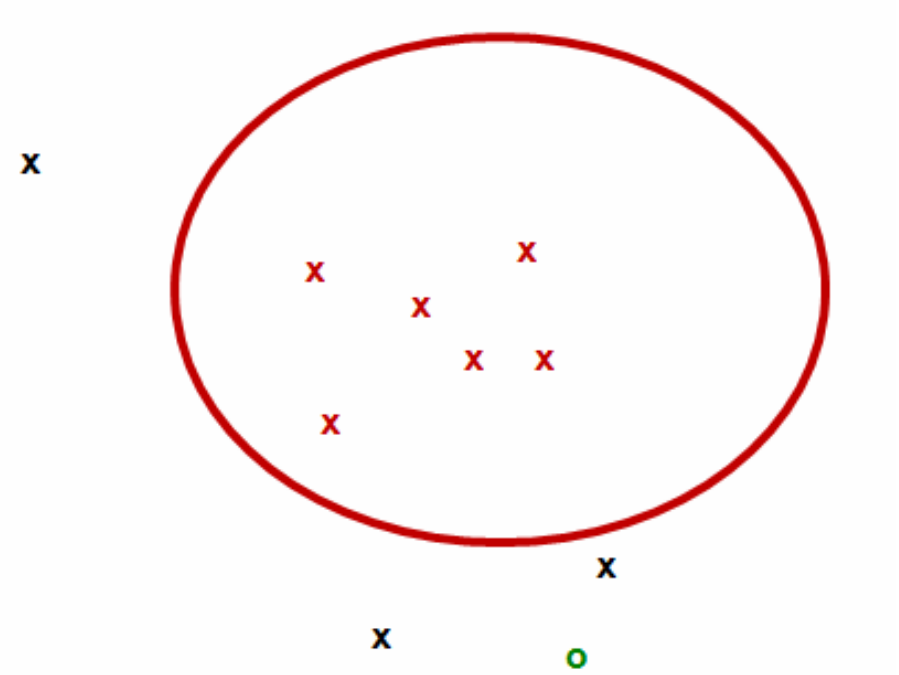
Rojo muestra documentación relevante para el análisis

Actividad inventiva de la 2ª realización



Rojo muestra documentación relevante para el análisis

Infracción por equivalencia



Rojo muestra documentación relevantes para el análisis

Sólo un IET que mostrara una X respecto a una patente anterior debería ser interpretado como que "*el examinador ve "equivalente" la solicitud estudiada*"

Actividad inventiva

Aproximación problema-solución

- ¿Cuál es el estado de la técnica más cercano?
- ¿Cuál es la diferencia, respecto a los elementos técnicos reivindicados, entre la invención reivindicada y el estado de la técnica más cercano?
- ¿Cuál es el efecto técnico causado por esta diferencia?
- ¿Cuál es, por tanto, el problema técnico objetivo que subyace a la invención reivindicada?
- A partir del conocimiento completo del estado de la técnica ¿Hubiera sido obvio para el experto en la materia reconocer el problema y solucionarlo de la manera indicada?

Estado de la técnica más cercano

- La elección del estado de la técnica más cercano puede supeditar todo el análisis
- No debería ponerse en discusión nunca, al menos en las demandas de nulidad, pero siempre se hace ¿Por qué?

Ningún estado de la técnica es descartable como más cercano

EPO Guidelines. 5.1 Determination of the closest prior art

The closest prior art is that which in one single reference discloses the combination of features which constitutes the most promising starting point for a development leading to the invention. In selecting the closest prior art, the first consideration 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. In practice, the closest prior art is generally that which corresponds to a similar use and requires the minimum of structural and functional modifications to arrive at the claimed invention (see T 606/89).*

In some cases there are several equally valid starting points for the assessment of inventive step, e.g. if the skilled person has a choice of several workable solutions, i.e. solutions starting from different documents, which might lead to the invention. If a patent is to be granted, it may be necessary to apply the problem-and-solution approach to each of these starting points in turn, i.e. in respect of all these workable solutions. In the event of refusal, however, it is sufficient to show, on the basis of one relevant piece of prior art in respect of at least one of these solutions, that the claimed subject-matter lacks an inventive step. In such a situation, ***there is no need to discuss which document is "closest" to the invention****; the only relevant question is whether the document used is a feasible starting point for assessing inventive step (see T 967/97, T 558/00, T 21/08, T 308/09 and T 1289/09).. **This is valid even if the problem identified in a problem-solution reasoning may be different from the one identified by the applicant/patentee***

Kluwer Patent Blog

CASE LAW, SPAIN

Spain : Ruling No. 159/2017, Court of Appeal of Barcelona, AUTO Nº 159/2017, 27 December 2017

Adrian Crespo (**Clifford Chance**) / **May 23, 2018** / **1 Comment**

In preliminary injunction proceedings, the influential Barcelona Court of Appeal held that reasons of "congruence" bind the court to basing the assessment of inventive step strictly on the particular prior art document chosen as the closest prior art by the party challenging its validity, regardless of whether that choice is technically and objectively justified. This could kick start a worrisome trend in Spanish revocation proceedings that is deeply inimical to the proper application of the problem-solution approach. The Court also made findings on the impact of decisions of the Opposition Division on Spanish injunctions.

A full summary of this case has been published on **Kluwer IP Law**.

Auto APB 159/2017, 27,12,2017

34. Ahora bien, discrepamos de la forma en la que el juez de instancia ha descrito el problema técnico objetivo al aplicar este método. Para ello, partiendo del documento del estado de la técnica más próximo a la reivindicación cuestionada, hemos de determinar cuáles son las diferencias técnicas, tanto estructurales como funcionales, entre lo divulgado en dicho documento y la reivindicación cuestionada. Una vez determinadas esas características diferenciales habremos de identificar el efecto técnico que producen y, partiendo de ese efecto, **formular el problema técnico objetivo**.

¡El problema técnico objetivo no debería usarse para definir el estado de la técnica más próximo, pues éste sólo se debe definir una vez determinado el estado de la técnica más cercano!

Ejemplo

- Reivindicación: Mesa metálica con 3 patas
- Problema técnico planteado por el titular: evitar que la mesa trastabille

- Estado técnica:
  - D1. Mesa de 4 patas que incorpora un elemento telescópico en una pata para evitar que trastabille
  - D2. Mesa de madera con 3 patas que evita molestias a los comensales al haber menos patas

- ¿Estado de la técnica más cercano?
- ¿Problema técnico **objetivo** asociado?

¡A veces no protegemos inventos sino que inventamos patentes!

La misión del agente de patentes y de los abogados es defender los intereses de su cliente dentro del marco legal y la práctica existente en los tribunales y las oficinas de patentes

(Reformulación) Problema técnico

EPO Guidelines, Parte G – Patentability, Chapter VII – Inventive step

5. Problem-and-solution approach

5.2 Formulation of the objective technical problem

...In the context of the problem-and-solution approach, the technical problem means the aim and task of modifying or adapting the closest prior art to provide the technical effects that the invention provides over the closest prior art. The technical problem thus defined is often referred to as the "**objective technical problem**".

The objective technical problem derived in this way may not be what the applicant presented as "the problem" in his application. The latter may require reformulation, since **the objective technical problem is based on objectively established facts, in particular appearing in the prior art revealed in the course of the proceedings, which may be different from the prior art of which the applicant was actually aware at the time the application was filed…**

…Reformulation might lead to the objective technical problem being less ambitious than originally envisaged by the application.

(Reformulación) Problema técnico

…The extent to which such reformulation of the technical problem is possible has to be assessed on the merits of each particular case. As a matter of principle any effect provided by the invention may be used as a basis for the reformulation of the technical problem, as long as said effect is derivable from the application as filed (see **T 386/89**). It is also possible to rely on new effects submitted subsequently during the proceedings by the applicant, provided that the skilled person would recognise these effects as implied by or related to the technical problem initially suggested (see **G-VII, 11** and **T 184/82**)…

Decisión Juzgado Mercantil 4 Barcelona – Aproximación inteligente

JM4 Barcelona 77/2018, 13.02.2018

3.27 El método problema-solución es solo un método jurídico para analizar la obviedad de un invento, cuya aplicación nunca tiene premisas verdaderas o falsas, sino mas o menos razonables. Si la parte que pretende la nulidad de la patente parte, como hemos dicho, de un compuesto descrito en el estado de técnica, que requiere mas modificaciones estructurales que otro, le será más difícil justificar la obviedad del invento cuestionado, pero creemos que no tiene mucho sentido enzarzarse en una discusión sobre si el documento propuesto por el titular es o no el mas cercano, lo importante siempre será si el documento seleccionado por el demandado forma parte del estado de técnica relevante.

3.28 Lógicamente el titular de la patente al oponerse a la pretensión de nulidad puede negar que el documento forme parte del estado de la técnica relevante o que constituya el punto de partida más prometedor, pero procesalmente no tiene sentido que analicemos si existe un documento del estado de la técnica mas cercano al propuesto por el demandado.

BoAs EPO en la línea decisión ES

- En muchas ocasiones los BoAs de la EPO en la elección del estado de la técnica más cercano habían seguido de forma estricta el aspecto “same object as the claimed invention”
- Esto podía llevar a un análisis completamente artificial de la actividad inventiva de las reivindicaciones
  - Escogiendo un antecedente con muy poco que ver con la invención aunque se dirigiera al mismo problema
  - Descartando documentos muy cercanos estructuralmente a la presunta invención y del mismo área
- Las nuevas decisiones van en la misma línea de la decisión española

T0855/15 de 10.01.2018

8.1 Firstly, the board considers 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. If a piece of prior art is "too remote" from an invention, it should be possible to show that the invention is not obvious to a skilled person having regard to this piece of prior art (see Article 56 EPC, and T 1742/12, point 9 of the reasons). 5.2 6. 7. 8. 8

8.2 Secondly, the board disagrees with the appellant's suggestion that it is relevant for the question of inventive step whether or not the "skilled person would [...] select" a piece of prior art "as a starting point to arrive at the invention" (see the grounds of appeal, page 4, paragraph 3). Article 56 EPC requires the assessment of whether an invention would be obvious to the skilled person "having regard to the state of the art". For this assessment, the deciding body will select one or more documents for consideration. However, no argument is required as to whether the skilled person would select a document. In fact, the board considers that a consideration of what the skilled person would do, in particular whether the skilled person "would select" a document, in order "to arrive at the invention as claimed" would amount to hindsight reasoning, because the skilled person would have to be assumed to know the invention before an argument could be made as to what he would do in order "to arrive at" it.

T2057/12 de 09.05.2018

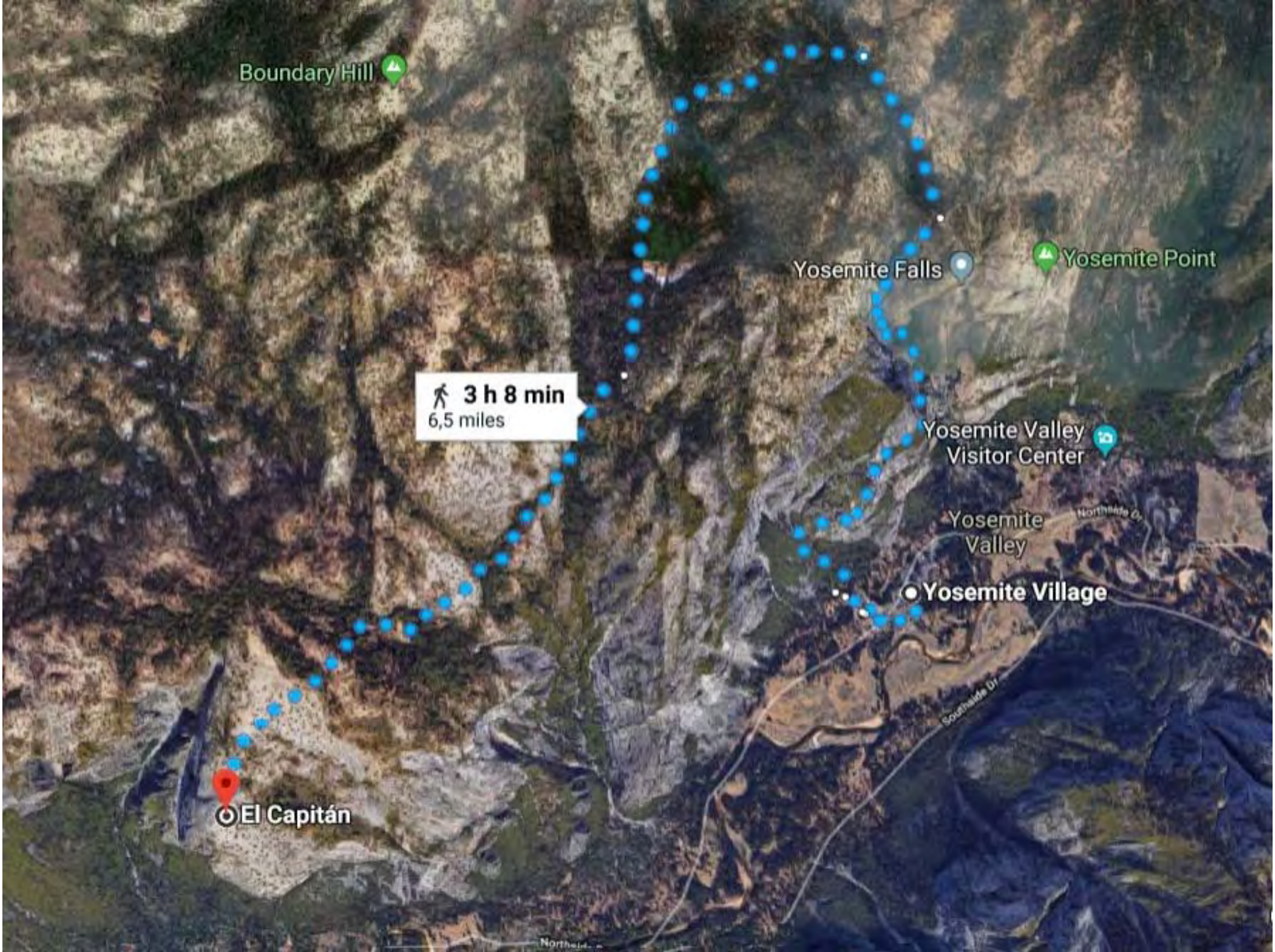
3.2.2 … It is generally accepted that the closest prior art normally discloses an item of prior art which shares a common purpose with the claimed subject-matter or aiming at the same objective... This approach appears to rely on the assumption that the skilled person would only possibly arrive at the claimed invention when starting from a document which shares a common or similar purpose with the claimed invention. In other words, this approach seems to exclude from the group of possible candidates as closest prior art disclosures which belong to technical fields remote from the field of the invention. The jurisprudence of the Boards of Appeal puts also much emphasis on the similarity of the technical problem to be solved by the item of prior art to be selected... These approaches have in common to limit the extent of the prior art to be considered when searching for the closest prior art. **It is, however, questionable whether they are in agreement with an analysis of inventive step which should be objective and should hence take into account all realistic circumstances which would lead to the claimed subject-matter**…

The principles developed by the jurisprudence of the boards of appeal, recalled above, would then lead to searching for the closest prior art in a totally different technical field… although the claimed invention would be the same... In a recent decision, it was considered that the remoteness of a piece of prior art did not, in itself rule out an assessment of inventive step in view of that prior art. **It was further held, that if a piece of prior art was too remote from an invention, it should be possible to show that the invention was not obvious to a skilled person having regard to this piece of prior art** (cf. T 855/15…. The present Board agrees with these findings. It can indeed not 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. Such a scenario, rather unusual**, cannot rely on mere speculation, but must be supported by sufficient evidence and argumentation**…

Consequently, arguments or evidence should be provided as to why the skilled person in a specific technical field would have indeed envisaged selecting a document in a remote field of technology as closest prior art or, alternatively, whether he would have indeed considered adapting a prior art disclosure originating from his technical field to implement it in a remote technical field.

“Altura inventiva”


NATIONAL
GEOGRAPHIC


Boundary Hill
Yosemite Falls
Yosemite Point
3 h 8 min
6,5 miles
Yosemite Valley
Visitor Center
Yosemite
Valley
Yosemite Village
El Capitán

KSR Int'l Co v. Teleflex Inc (2007)

(c) The flaws in the Federal Circuit's analysis relate mostly to its narrow conception of the obviousness inquiry consequent in its application of the TSM test. The Circuit first erred in holding that courts and patent examiners should look only to the problem the patentee was trying to solve. Under the correct analysis, any need or problem known in the field and addressed by the patent can provide a reason for combining the elements in the manner claimed. Second, the appeals court erred in assuming that a person of ordinary skill in the art attempting to solve a problem will be led only to those prior art elements designed to solve the same problem…

…It is common sense that familiar items may have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle…

Finally, the court drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. Rigid preventative rules that deny recourse to common sense are neither necessary under, nor consistent with, this Court's case law.

Late-filed evidence

¿Cuándo es aceptable admitir pruebas posteriores a la solicitud para defender la actividad inventiva de una reivindicación?

Este concepto es diferente de la reformulación del problema técnico y requiere requisitos independientes

- Puede haber base para reformular el problema técnico pero no para aportar datos con posterioridad a la solicitud

Decisión T1329/04

***Case Law of the Boards of Appeal of the EPO*, 8ª ed. P. 182**

*In **T 1329/04** it was stated that the definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, required that it was **at least made plausible** by the disclosure in the application that **its teaching indeed solved the problem it purported to solve**. Therefore, even if supplementary post-published evidence might, where appropriate, also be taken into consideration, it could not serve as the sole basis for establishing that the application did indeed solve the problem it purported to solve.*

Decisión T0488/16 - Dasatinib

- La solicitud de patente EP1169038 describía amplias fórmulas de Markush que englobaban, entre otros, al dasatinib
- Describía explícitamente 580 productos, entre ellos el dasatinib
- Se incluía una frase en la que se indicaba que dichos productos se habían probado en uno o más ensayos y que habían mostrado actividad: (p. 50 WO00/62778): "*Compounds described in the following Examples have been tested in one or more of these assays, and have shown activity*"
- La patente se limitó finalmente durante el recurso únicamente a dasatinib
- El solicitante aportó posteriormente datos que mostraban sin lugar a dudas la actividad del dasatinib (fármaco comercial)
- La patente se revocó en recurso frente a la EPO por falta de actividad inventiva

No se admiten pruebas posteriores

4. Post-published documents...

4.2 It is established jurisprudence of the boards of appeal that the assessment of inventive step is to be made at the effective date of the patent on the basis of the information in the patent together with the common general knowledge then available to the skilled person. Post-published evidence in support that the claimed subject-matter solves the technical problem the patent in suit purports to solve may be taken into consideration, if it is already plausible from the disclosure of the patent that the problem is indeed solved (see Case Law of the Boards of Appeal, 8th edition, I.D.4.6; T 1329/04, point 12 of the Reasons; T 1043/10, point 12 or the Reasons). Thus, for post-published evidence to be taken into account, it is necessary to establish whether or not the asserted activity has been made sufficiently plausible for dasatinib at the effective date of the patent in suit. Basis for this assessment is the application as filed and the common general knowledge of the person skilled in the art at the filing date.

On page 50, line 4 to page 53, line 18, the application refers to assays "which can be employed in ascertaining the degree of activity of a compound ("test compound“) as PTK inhibitor" (see page 49, lines 29 to 30). The assays are generically described and refer to the "protein kinase of interest" and the "test compound" or "compounds of interest" to be assayed. No further details are provided in this respect. Nor are any results, for example IC or Ki values, provided. Indeed, there is no evidence at all in the application as filed that shows that any of the compounds falling within the scope of formula I, let alone dasatinib, is active as an inhibitor for any of the specific protein tyrosine kinases, except a mere assertion on page 50, lines 1 to 2 with reads that "Compounds described in the following Examples have been tested in one or more of these assays and have shown activity." No further information is provided.... In the board's judgement, a mere verbal statement that "compounds have been found active" in the absence of any verifiable technical evidence is not sufficient to render it credible that the technical problem the application purports to solve,...

…In the present case, there is also no evidence on file showing that, at the date of filing, the skilled person was in the possession of common general knowledge which, even in the absence of data, made it plausible that the compounds of the invention, in particular dasatinib, could be expected to show PTK inhibitory activity...

4.9 The board agrees with the appellant insofar as it is not always required to include experimental data or results in an application (see T 578/06, point 13 of the Reasons). It is however a *conditio sine qua non* that it is shown that the technical problem underlying the invention was at least plausibly solved at the filing date. If, as in the present case, the nature of the invention is such that it relies on a technical effect, which is neither self-evident nor predictable or based on a conclusive theoretical concept, at least some technical evidence is required to show that a technical problem has indeed been solved.

5.6 It follows from the above that the problem to be solved has to be defined in a less ambitious way, namely as the provision of a further chemical compound.

5.7 According to the jurisprudence of the boards of appeal, a chemical compound is not patentable merely because it potentially enriches chemistry and structural, since originality has no intrinsic value or significance for the assessment of inventive step as long as it does not manifest itself in a valuable property in the widest sense, an effect or an increase in the potency of an effect… In other words, the mere provision of a chemical compound capable of being synthesised, which was not contested, and not showing any effect does not require inventive ingenuity. The structural uniqueness of dasatinib alone cannot therefore support an inventive step.

5.8 The appellant's additional arguments in favour of an inventive step were focused on the PTK inhibitory activity of dasatinib (see point XI above). They are, however, not pertinent in a situation where this effect could not be acknowledged and the problem to be solved was merely the provision of further chemical compound.

Decisión T0950/13 – Uso Dasatinib

- La patente EP1610780 proviene de la solicitud internacional WO04/85388, en la que se pedía protección por el uso de compuestos incluidos en una fórmula de Markush, entre los que se encontraba el dasatinib, contra ciertos tipos de cáncer
- El uso del dasatinib se protegía de forma específica (reivs. 3-4)
- La patente se concedió limitada al uso de dasatinib
- La patente fue revocada en oposición
- El oponente no se presentó a la vista oral en el BoA (la discusión se centró en suficiencia de la descripción y la patente fue remitida a la división de oposición)

Plausibilidad de un efecto no implica plausibilidad de todos los relacionados

3.2 Article 83 EPC stipulates that the patent shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

In relation to claims directed to a second medical use of a compound, it is established jurisprudence of the boards of appeal that Article 83 EPC is complied with if the content of the application as filed or common general knowledge at the relevant date enables the skilled person to prepare the claimed compound or compounds - which was not disputed in the present case - and the claimed treatment can be achieved in a reliable and reproducible manner. This means that **either the application must provide suitable evidence for the claimed therapeutic effect or it must be derivable from the prior art or common general knowledge. Post-published evidence may be taken into account, but only to back-up the findings in the application in relation to the use of the compound(s) as a pharmaceutical** (cf. T 609/02, point 9 of the Reasons).

3.6 The application does not contain experimental evidence for dasatinib's BRC-ABL kinase inhibitory activity. However, the disclosure of experimental results in the application is not always required to establish sufficiency, in particular if the application discloses a plausible technical concept and there are no substantiated doubts that the claimed concept can be put into practice…

…the board is satisfied that the application discloses at least a plausible technical concept, namely that dasatinib based on its functional equivalence to imatinib as a BRC-ABL kinase inhibitor is suitable in the treatment of CML. There are no reasons apparent to the board as to why a skilled person would a priori regard this teaching as incredible or implausible. As a consequence, the post-published evidence in the form of document (2), which confirms the BRC-ABL kinase inhibitory activity of dasatinib (see table 2, first entry) and therefore merely backs-up the teaching derivable from the application, can be taken into account…

3.13 This conclusion, however, does not apply to the subject-matter of claim 2 of the main request, which is directed to the use of dasatinib for the manufacture of a medicament for oral treatment of CML, which is resistant to STI-571 (= imatinib).

3.13.1 It was known in the art that primary and secondary resistance to imatinib is a major problem in patients with CML… Several mechanisms of resistance were known including BRC-ABL overexpression, reduced cellular up-take mediated by the multi-drug resistance P-glycoprotein and specific mutations within the ATPbinding site resulting in diminished binding of imatinib… The appellant's argument that… imatinib-resistant CML in the application would be understood by the skilled person as a clear disclosure that dasatinib inhibits mutation forms of BRC-ABL (see document (8), points 29g) and 36) is therefore not accepted.

3.13.2. The application as filed contains no information at all, neither in the form of experimental data nor in the form of a plausible technical concept, that dasatinib is suitable in the treatment of those patients with imatinib-resistant CML. The functional analogy to imatinib as BRC-ABL kinase inhibitor is not helpful in this context and cannot explain why dasatinib should be active, when imatinib is, or has become, inactive.

3.14 The board therefore concludes that the claimed therapeutic use, i.e. the treatment of CML which is resistant to imatinib, has not been made plausible to the skilled person either from the teaching of the application as filed or from common general knowledge at the relevant date.

La plausibilidad de un efecto técnico no implica que se pueda aceptar cualquier efecto técnico relacionado o incluso “más restringido” que el inicial

Formulación de un problema técnico

- Diferentes pasos a seguir:
  - Debe haber base en la memoria para plantear un problema técnico
  - Si se presenta nueva documentación, debe ser plausible el efecto técnico a partir de la información en la solicitud tal como se presento y/o el conocimiento general común para su aceptación
  - Con la información disponible (aceptada) se debe verificar que se trata de un problema técnico objetivo que la invención soluciona en todo el ámbito de la reivindicación

EJEMPLO COMBINACIÓN FÁRMACOS

- Estado de la técnica: A y B antitumorales. También se han descrito diferentes combinaciones con estos principios activos, pero no la concreta A y B
- Patente:
  - Reiv.1: A+B / Reiv. 2: Uso A+B como antitumoral
  - Memoria: Mayor actividad, efecto sinérgico, menos efectos secundarios
  - No datos experimentales
- "Late-filed" documento:
  - Producto eficaz, y sorprendente contra tumor específico
  - Evita la resistencia que crea el antitumoral B
  - Efectos secundarios similares pero no Mucositis (A y B sí la producían)

¿VALIDEZ?

EJEMPLO USOS FÁRMACO

- Estado de la técnica: Fármaco X como antihipertensivo
- Patente:
  - Reiv.1: Uso de X contra enfermedades 1, 2, 3, 4, 5, 6.... Diurético,...
  - Memoria: Descripción de todos los usos. Frase indicando que es útil contra todos y cada uno de ellos. Argumenta ventajas genéricas
  - No datos experimentales
- “Late-filed” documento:
  - Producto eficaz como diurético
  - Comparativa con producto de referencia y tiene ventajas

¿VALIDEZ?

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