

D YOUNG & CO PATENT NEWSLETTER *no.90*

August 2022

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Unified Patent Court
Doors expected to
open in early 2023!

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As the heat from the summer begins to subside, we are gearing up for the entry into force of the UPC. This edition of the newsletter looks at the latest developments on the UPC, commentaries on the relevance of clinical trial protocols as prior art, issues concerning machine learning patents and much more. As ever, please contact your D Young & Co representative should you have any questions on these topics.

Simon O'Brien, Editor

Webinars



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Partners Simon O'Brien and Anthony Latham present our regular webinar round up of important and recent European biotech case law.

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Events



IPO Annual Meeting

Los Angeles, USA, 18-20 September 2022

Garreth Duncan will be attending this event with trade mark partner Jackie Johnson.

CIPA IP Paralegal Conference 2022

London, UK, 07 October 2022

William Burrell will be speaking about "Post Brexit UK Design Registration Tips and Practices".

TechBio UK 2022

London, UK 13 October 2022

Jennifer O'Farrell and Robbie Berryman will be attending this conference concerning data-driven discovery in life sciences.

C5 20th Global Forum on Life Science Patent Term Extensions

Munich, Germany 19 October 2022

Garreth Duncan will be discussing SPCs in a masterclass panel, together with a judge and in-house counsel.

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Unified Patent Court Doors expected to open in early 2023!

The UPC Agreement can be expected to enter into force in early 2023



In its second meeting in Luxembourg on 08 July 2022, the Administrative Committee of the Unified Patent Court (UPC) has taken significant steps towards the setting up of the Unified Patent Court.

Among other things, the Administrative Committee has adopted the UPC's Rules of Procedure and Table of Fees, both of which will enter into force on 01 September 2022, in good time for application during the sunrise period, which could start in the fourth quarter of 2022.

In regard to the Court of First Instance, the Administrative Committee has confirmed Local Divisions in Vienna, Austria; Brussels, Belgium; Copenhagen, Denmark; Helsinki, Finland; Paris, France; Düsseldorf, Hamburg, Mannheim and Munich, Germany; Milan, Italy; The Hague, Netherlands; Ljubljana, Slovenia; and Lisbon, Portugal. A regional division, the Nordic-Baltic division, is to be mainly located in Stockholm, Sweden.

Assisted by the Advisory Committee, the Administrative Committee prepares the appointment of legally qualified judges and technically qualified judges of the Court based on a recommended list of most suitable candidates. According to Art. 15(1) UPC Agreement, "[j]udges shall ensure the highest standards of competence and shall have proven experience in the field of patent litigation". Taking the court's decisions according to Art. 24 UPC Agreement based on European Union law, the UPC Agreement, the European Patent Convention, and other international and national laws relevant to the Contracting member states of the UPC, these judges will

be key to the success of the Unified Patent Court, being a "common court" for several member states of the European Union.

Following the meeting of the Administrative Committee, the UPC can now reasonably be expected to open its doors in early 2023.

At least three calendar months before entry into force of the UPC Agreement the "sunrise period" will start. During the sunrise period, "classic" European patent applications, European patents and related supplementary protection certificates (SPCs) - but not unitary patents - may be, by applicants, proprietors and holders, respectively, safely opted-out from the exclusive competence of the new UPC according to Art. 83(3) of the UPC Agreement before an action against any of them can be brought before the UPC.

Thus, bearing in mind that the UPC Agreement can be expected to enter into force in "early 2023", any applicants or proprietors being sceptical of the new court are advised to identify the European patent applications, European patents and SPCs that they wish to opt-out, such that any application to opt-out may be timely lodged with the registry of the UPC during the sunrise period. The sunrise period is cautiously expected to start between September and December 2022.

Applicants, proprietors and holders considering opting out European patent applications, European patents and SPCs, respectively, are advised to contact their representatives as soon as possible.

Author:
Hanns Juergens-Grosse



T 1123/16 & T 2963/19

Clinical trial protocols as closest prior art

Two recent decisions from the EPO Board of Appeal considered whether clinical trial protocols provide the skilled person with a reasonable expectation of success. The decisions add to the growing body of case law in this area.

T 1123/16: Eosinophilic bronchitis/GLAXO

This appeal stems from the opposition division's decision to reject the opposition.

Claim 1 related to "a composition comprising at least one neutralising humanised anti-human-IL-5 antibody for use in treating a human suffering from steroid-dependent eosinophilic bronchitis, characterised in that the steroid is prednisone and wherein the prednisone is reduced by at least about 90% in said human after treatment."

The Board of Appeal considered the disclosure of D1, a **phase II clinical trial**, an appropriate starting point for the assessment of inventive step, as it concerned the treatment of patients with the same medical condition (steroid-dependent eosinophilic bronchitis) using the same substance (a humanised anti-IL-5 antibody) with the same objective (a reduction in prednisone administration). However, D1 did not disclose a therapeutic effect, since it did not disclose any results of the clinical trial; nor did it disclose the minimum level of prednisone-sparing effect (90%).

According to established case law, clinical trial protocols are considered to provide the skilled person with a **reasonable expectation of success**, unless the state of the art provides the skilled person with an **expectation of failure**. The reason being that clinical trials are based on existing favourable scientific data (pre-clinical testing in vitro and on animals), taking in to account ethical and economical considerations, and are not based on a general "try-and-see" attitude (see **T 2506/12** and **239/16**).

In this case, the Board of Appeal therefore considered whether the state of the art provided the skilled person with an **expectation that the treatment would fail**. The respondent submitted that several

documents concerning asthma treatment showed that there was a **negative expectation** regarding a successful treatment based on an antibody to IL-5. However, the Board of Appeal did not consider this line of argument relevant as the claim at hand did not require that the patients suffer from asthma. Thus, it concluded the skilled person had **no reason** to expect that the treatment described in D1 **would not succeed**.

With regard to the level of reduction in prednisone specified in the claim, the Board of Appeal considered this to be a **consequence** of pursuing the treatment described in D1, for which the skilled person had a **reasonable expectation** that a prednisone reduction would be achieved.

Accordingly, the Board of Appeal overturned the opposition division's decision as the subject-matter of claim 1 lacked an inventive step in view of the clinical trial disclosed in D1.

T 2963/19: Liposomal irinotecan/IPSEN

In **T 2963/19**, claim 1 related to a combination therapy for treating pancreatic cancer, comprising administering defined amounts of liposomal irinotecan, 5-fluorouracil and leucovorin. The patent was revoked at first instance for lacking an inventive step in view of D15b, a **phase III clinical trial**. The clinical trial protocol differed from the disclosure of the claimed subject-matter in that it did not disclose the actual effective and safe treatment of the patients (a therapeutic effect). Nor did the clinical trial protocol specify the order in which the drugs were administered or the distinction in the starting dose depending on the allele status of the patient, as required by the claim.

Notably, in **T 2963/19**, the Board of Appeal accepted that the development of therapy of gemcitabine refractory pancreatic cancer represented a particular challenge, due to the poor prognosis and low success rates of clinical trials. Furthermore, the approval of a clinical study depends on the assessment of the foreseeable risks in relation to the anticipated benefit in terms of relevance of the findings, which does not necessarily imply an expected positive outcome. Thus, the

Board of Appeal was not convinced that the disclosure of D15b **itself** provided the skilled person with a reasonable expectation that the treatment would be safe and effective.

The decision is in line with existing case law that clinical trials provide an expectation of success, unless the state of the art suggests otherwise. The Board of Appeal added that: "The considerations in **T 239/16** regarding the expected success following the approval of a clinical trial are evidently **closely linked to the further circumstances of the case** decided therein and cannot be extrapolated to the present appeal case. The same applies with respect to similar considerations in **T 2506/12**" (emphasis added).

However, the Board of Appeal considered that the disclosure of D15b was **not to be considered by itself**. For example, D15b was preceded by reports of beneficial effects of liposomal irinotecan combination therapy in Phase I investigations, and non-liposomal irinotecan in Phase II studies. The patentees themselves had relied upon these disclosures in their arguments for sufficiency and plausibility. Thus, the Board of Appeal concluded that, in as far as the patent proposes the claimed dosage regimen to be safe and effective in view of these prior disclosures, **the same considerations apply** in assessing whether a positive outcome could reasonably be expected from the clinical trial in D15b. Accordingly, claim 1 was obvious in view of D15b.

Take home messages

These decisions are in line with existing case law that clinical trials provide the skilled person with a reasonable expectation of success, in the absence of existing prejudices. Considerations regarding an expectation of success in view of a clinical trial protocol are likely to be highly dependent on the facts of each case. Reciting an unknown but inherent result of the obvious treatment may have no bearing on the assessment of inventive step.

Author:
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Machine learning

Issues concerning the grant of ML patents at the EPO

How much information should you include in your machine learning (ML) patent application to give it the best chance of being granted by the European Patent Office (EPO)?

As explained in our previous article (see link below), the answer to this question relies on a careful balance between disclosing enough information to meet EPO requirements, and not disclosing so much that competitors may gain commercially valuable information when the patent application is published.

Related article

"Practical considerations for patenting AI", 20 October 2020, Robbie Berryman: www.dyoung.com/en/knowledgebank/articles/patenting-ai-considerations

In this article, we discuss two issues to consider for obtaining ML patents.

1. Sufficiency

Article 83 of the European Patent Convention (EPC) requires that: "The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art." For ML patents, the requirements of Article 83 are particularly important when it comes to training data.

For example, in T 0161/18, the EPO Board of Appeal found that a patent application does not meet the requirements of Article 83 if: "... the application does not disclose **which input data are suitable for training the artificial neural network** of the invention, **or at least one data set suitable** for solving the present technical problem ..." (Reasons, 2.2).

Similarly, in T 1191/19, a patent application was deemed not to satisfy Article 83 because it did not disclose: "... any **example set of training data** ... The application does not even disclose the **minimum number of patients from which training data should be compiled** to be able to give a meaningful prediction ..." (Reasons, 4.1).

So, a description of the training data required to training a ML model is clearly important. In particular, the EPO appears to require disclosure of:

- which input data (for example, the minimum requirements of that data) would be suitable for training the ML model to solve the technical problem at hand; and/or
- at least one example set of training data suitable for training the ML model.

2. Inventive Step

In both of the above Board of Appeal decisions, the patent applications were also found to lack an inventive step. For a patent to be granted, the claimed invention needs

to be both new and inventive – that is, "not obvious to a person skilled in the art" (Article 56 EPC). In applying this requirement, the two Boards of Appeal found that **the mere application of machine learning to a known problem is not enough for an application to be considered inventive**.

For example, in both T 0161/18 and T 1191/19, the Board of Appeal held that: "... the mere application of a known machine learning technique to problems in a particular field is a general trend in technology ... and cannot be inventive as such ..." (T 1191/19, Reasons, 3.2).

So, the EPO is unlikely to consider a ML patent to be inventive unless there is something about the model or how the model is used which is specifically adapted to the specific use case of the model.

Note also that the EPO requires the claimed invention to provide some technical improvement, so applying ML to a non-technical problem (for example, in relation to a business method or similar) is unlikely to lead to a granted European patent (T 0755/18, Reasons, 3.2).

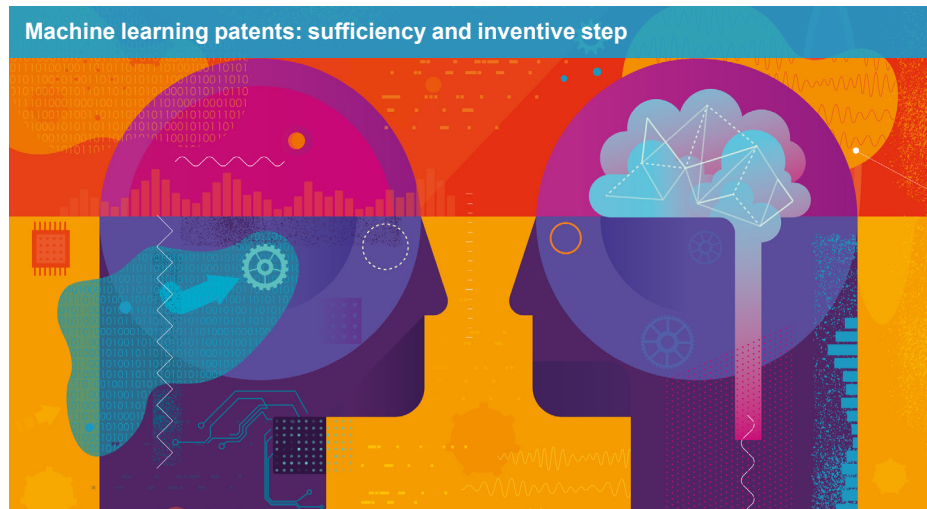
Conclusion

We can see, therefore, that the Board of Appeal at the EPO does not consider the requirements of Article 83 EPC to be met unless a patent application identifies which input data (for example, the minimum requirements of that data) would be suitable for training the ML model, and does not consider a ML application to be inventive unless there is something about the model or how the model is used which is specifically adapted to the specific use case of the model and provides a technical improvement.

This means that a claim to the mere idea of applying machine learning to a known problem (with no further detail on how the model is used or implemented) is unlikely to lead to a granted European patent.

Author:

Jessica Steven-Fountain



UK R&D tax credit landscape

Upcoming proposed changes



In what is clearly good news for many, the UK Government has drafted a number of pleasing changes to the UK research and development tax credit landscape. These changes follow from the recent consultation which the UK Government held on this point, which we previously reported on.

One of the most exciting changes is the broadening of what can count as “qualifying expenditure” in the context of the scheme. Such qualifying expenditure will now include the costs of datasets and cloud computing. Pleasingly as well, qualifying expenditure will now also include pure mathematics. These changes will have a tremendous impact for many, particularly those operating with algorithms or AI, or those operating in the risk analysis sector, where costs related to these activities may soon be claimable under the R&D tax credit scheme.

In mitigation against the above, the UK Government is also keen for the scheme to be better directed at R&D which is based in the UK. With this in mind, and where any R&D is subcontracted out, or is provided by external workers, future claims under the scheme will either need to relate to UK expenditure or qualifying overseas expenditure. Such overseas expenditure will be heavily caveated to activities undertaken overseas which are necessary due to geographical, environmental or social conditions not present or replicable in the UK. Importantly, any considerations with respect to performing such activities overseas, as opposed to in the UK, because of it being merely cheaper to perform overseas, or because of there being a lack of available workers in the UK, will specifically be excluded as valid factors as to why such overseas expenditure should be allowed under the scheme.

The above changes to the R&D tax credit scheme will apply for accounting periods beginning on or after 01 April 2023.

As part of the above changes to the scheme, the UK Government is also keen to tackle potential abuses under the scheme. So a number of additional, more practical, changes have also been proposed to the scheme, which include:

- for those companies that have not recently made an R&D tax credit claim, they will need to inform HMRC, in advance, that they intend to make a claim. This notification must be made digitally, and within six months of the end of the period to which the claim relates;
- claims will have to be made digitally; and
- claims will have to break down the costs across qualifying categories and provide a brief description of the R&D which is being claimed for tax relief. Each claim will also need to be endorsed by a named senior officer of the company (inferably for accountability purposes, and for providing points of contact for each relevant expenditure that is being claimed).

It is to be noted that these changes are still at the draft legislation stage, and so may be the subject of slight change prior to implementation. In any case, the thrust of the proposed changes are clearly well intended, and will no doubt be well received by many... particularly for those entities operating in the pure mathematics and cloud computing sectors, who may soon be able to make better use of the R&D tax credit scheme.

Author:
William Burrell



Related article
UK Government consultation:
R&D tax credit scheme
<https://dycip.com/uk-tax-22>

Further information on the upcoming proposed changes can be found at:
<https://dycip.com/uk-gov-tax-210722>

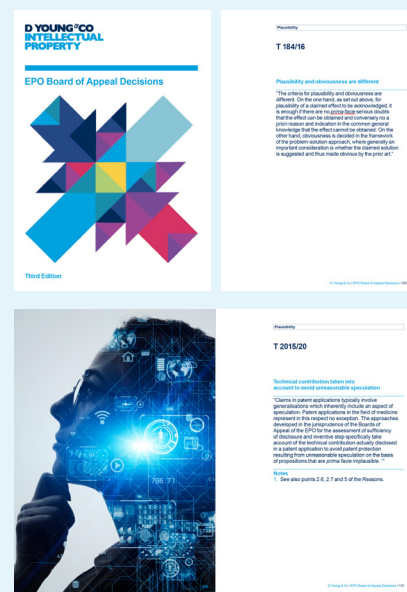
EPO Board of Appeal Decisions

Third edition ebook

The third edition of our book of decisions from the European Patent Office (EPO) Boards of Appeal is now available as an ebook download. The selected Board of Appeal decisions have been chosen on the basis of many years of experience in arguing cases before the EPO. In general, they represent some of the most useful and frequently cited decisions used by D Young & Co's patent group during both our defence of and opposition to European patents. In this third edition we have included a number of additional cases and an updated section on the Rules of Procedure of the Boards of Appeal of the European Patent Office. We have also included a new section on oral proceedings being held by video conference (ViCo).

Contributors

The book was written and co-edited by members of our biotechnology, chemistry and pharmaceuticals patent group - Charles Harding, Antony Latham, Matthew Gallon and Rachel Bateman.



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www.dyoung.com/epo-book-2021

Sandoz v Teva UK

Revocation of UK formulation patents for blockbuster drug, Apixaban

Eliquis®, the Bristol Myers Squibb (BMS) and Pfizer apixaban product, was recently ranked in the top five pharmaceutical products sold worldwide, with a significant increase in demand resulting from the Covid-19 pandemic. Enforceability of BMS and Pfizer's patent portfolio will clearly be critical to the ongoing success of this blockbuster drug.

Following revocation proceedings brought by Sandoz and Teva Pharmaceutical Industries (Teva), earlier this year the High Court of England and Wales invalidated BMS's basic European (UK) apixaban patent and supplementary protection certificate (SPC), for lack of plausibility (that is, Agrevo obviousness and/or insufficiency).

Recently, the High Court has also assessed the obviousness of four of BMS and Pfizer's European (UK) patents apixaban formulation patents, following further revocation proceedings brought by Sandoz and Teva. The European patents belong to the same family, and have all recently been revoked by the EPO's opposition division. However, these decisions are either under appeal or awaiting appeal.

The key claim to be addressed in the UK proceedings was claim 1 of EP3246021B (EP'021), in a proposed amended form. This claim was directed to a tablet comprising up to 5 mg crystalline apixaban particles having a specified particle size ($D_{90} < 89 \mu\text{m}$), and a diluent/carrier; the formulation having a particular dissolution rate ($\geq 77\%$ drug dissolved within 30 minutes, measured under standard conditions). It was accepted that the validity of the other three patents would stand or fall with EP'021.

On that basis, the skilled team was taken to include a clinician, who would define the desired formulation; and a formulator, who would aim to prepare it.

At the effective date, apixaban was well-known to be a promising anti-coagulant alternative to warfarin, and had reached advanced stage clinical trials.

The judge found the UK designations of the four European patents to be invalid



The parties agreed that a review article concerning apixaban's development would motivate the clinician to recommend preparation of 2.5 and 5 mg immediate release tablets, which had been used in the described clinical trials.

Starting from the review article, the necessary steps to the claim were taken to be the choice of particle size and dissolution rate. The remaining features were not considered to contribute to inventive step.

For most tablet-formulated drugs to reach the systemic circulation, the tablet must first disintegrate in the stomach; then, the active ingredient must dissolve into gastrointestinal fluids, and permeate across tissue membranes at the gastrointestinal tract's absorption site.

The parties agreed that, at an early stage in development, the formulator would routinely assess the equilibrium solubility of apixaban at the recommended doses. Accordingly, they would understand apixaban to be a class III drug (high solubility and low permeability) under the biopharmaceutics classification system (BCS).

Although equilibrium solubility tends to correlate with dissolution rate, they are different; sometimes a soluble drug is slow to dissolve, risking limited drug absorption.

BMS and Pfizer's expert believed that the skilled team would be so optimistic about the dissolution rate of a class III drug that it would not be tested. However, Mr Justice Meade disagreed. Given the complexity and expense of drug development, and risk to future process changes and biowaivers,

the judge decided that the formulator would not leave poor bioavailability up to chance. Instead, the formulator would aim to ensure a fast dissolution rate (such as 85% dissolution in 15 or 30 minutes) at an early stage.

Although a problem with the dissolution rate could not be predicted, assuming the formulator discovered a problem, the judge concluded that they would arrive at the claimed formulation on the basis of their common general knowledge alone. The formulator would first check the disintegration rate, and make any necessary improvements. An obvious way to improve any remaining dissolution issue was to reduce the particle size; and the claimed size ($D_{90} < 89 \mu\text{m}$) was well within the range typically used (~ 10 to $100 \mu\text{m}$).

Other obvious solutions were available, such as excipient optimisation. However, this was not considered to render the claimed solution any less obvious.

Conversely, if there was no problem with the dissolution rate, the claim makes no technical contribution.

Therefore, Mr Justice Meade found the UK designations of the four European patents to be invalid.

The judge was aware of the opposition division decisions. He acknowledged that different prior art had been taken into consideration at the EPO, but recognised that his reasoning is broadly consistent with that of the opposition division.

Author:
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T 3000/19

How do you solve a problem like video evidence?

A European Patent Office (EPO) Board of Appeal was recently asked to consider a case where an online video was cited against a patent application, with just one problem: the video was no longer available. In T 3000/19, the Board of Appeal addressed what should be done when electronic evidence can no longer be accessed and what actions should be taken to preserve such evidence.

Background and decision

Article 54 EPC is clear that the state of the art for an application contains everything publicly available prior to the priority date, including electronic videos. In T 3000/19, the Board of Appeal was asked to consider the refusal of an application on the basis of a prior art video. The video was cited by the examining division of first instance as a URL and a screenshot of the web page containing the video, as directed by the EPO Guidelines for Examination at the time. However, since the original first instance decision was issued the web page containing the video stopped functioning, meaning the Board of Appeal had no access to the cited video.

While the video was prior art for the application, the Board of Appeal decided that the content of the video could not be verified and therefore that the correctness of the original decision could not be reviewed. The Board of Appeal therefore remitted the case to the examining division for further prosecution. In addition, the Board of Appeal decided that the failure by the examining division to preserve the video such that it could be accessed by the Board of Appeal constitutes a substantial procedural violation, as the original decision was not sufficiently reasoned. This is despite the examining division following the EPO Guidelines for Examination at the time on how video evidence should be cited as prior art.

This case is, however, not the first time this issue has arisen. In T 3071/19, the Board of Appeal decided that the correctness of the original decision at first instance could not be decided without access to the cited video, and reached the same conclusion as in the

Is video evidence legitimate prior art?



present case. Therefore, what is of more interest in the present case is the Board of Appeal's additional comments regarding the citation of electronic evidence as prior art.

Analysis

The Board of Appeal provided extra discussion on the preservation of electronic evidence and noted the importance of continued accessibility to electronic evidence for the judiciary and interested third parties. The Board of Appeal also made reference to non-binding guidelines provided by the Council of Europe regarding how electronic evidence should be preserved. It is clear that this Board of Appeal intends that this case should act as guidance as to what steps the EPO must take to prevent a repeat of T3000/19. This is particularly evident as the present decision has been given the EPO's second-highest distribution code: "B", meaning the decision is distributed to all members of the Boards of Appeal.

The guidance suggests that special precautions should be taken to preserve electronic evidence. This includes collecting and securely storing the evidence in its original format and with standardised metadata to ensure the context of the evidence is preserved. At present, the EPO does not itself store video evidence, however the Board of Appeal have concluded that the EPO's current system for citing electronic evidence is not adequate. Therefore, the EPO may decide to put

procedures in place to preserve electronic evidence, however the cost of doing so is unclear and could be prohibitively high.

Importantly, the guidance from the Council of Europe referenced by the Board of Appeal also suggests that electronic evidence should only be used to the extent that it is strictly required for deciding a case. This raises the prospect of EPO examiners being discouraged from citing electronic evidence during prosecution of applications to avoid the EPO needing to implement provisions for collecting and storing large quantities of electronic evidence. This of course does not prevent third parties from citing video evidence during opposition proceedings.

Conclusion

This case highlights that while video evidence is legitimate prior art for a patent application, the fact that videos are harder to preserve may mean that examiners are hesitant to rely upon video evidence as prior art, unless the EPO changes its practices for citing electronic evidence. Just what this might mean for applications where the closest available prior art is an electronic video remains to be seen. What is clear, however, is that the current system for citing electronic evidence at the EPO is not fit for purpose and that changes must be made.

Author:
Ben Hunter



Artificial intelligence originating inventions

Can an AI system be designated as inventor?

Artificial Intelligence (AI) is a rapidly developing area of technology. AI systems are now capable of driving autonomous cars, performing translation of text, and assisting in healthcare and construction. AI systems are even capable of beating humans in games such as chess – an achievement which was originally considered out of reach for a computer. With the development of AI systems, the question arises: can an AI system be designated as an inventor under patent law?

The publication of the full decision for J 8/20 by the Board of Appeal answers a number of legal questions related to inventions which have been created by AI systems under European patent law.

Background

J 8/20 was an appeal against a decision to refuse the application EP 18 275 163, in which an AI system called DABUS was designated as inventor. The applicant was Dr Thaler (the inventor of DABUS).

At first instance, the application was refused on two grounds. In summary, these were:

1. a designation indicating a machine as inventor did not meet the requirements of Article 81 and Rule 19(1) EPC, because an inventor within the meaning of the EPC had to be a natural person; and
2. the statement indicating how the applicant acquired the right to the European patent did not meet the requirements of Articles 60(1) and 81 EPC, because a machine had no legal personality and could neither by an employee of the applicant nor transfer any right to the applicant.

The applicant then lodged an appeal against this decision.

With the appeal, the applicant (appellant) argued that the entity which comes up with the inventive concept was the deviser of the invention and should be recognised as such, since the public has a right to know

how the invention was made. Moreover, the appellant argued that Dr Thaler acquired the right to the invention as the employer of DABUS or successor in title to the invention.

Reason for the decision

In J 8/20, the Board of Appeal agreed with the grounds of refusal of the first instance decision. In particular, the Board of Appeal noted that the designated inventor has to be a person with legal capacity.

According to the Board of Appeal, this is not merely an assumption on which the EPC was drafted. It is the ordinary meaning of the term inventor.

Indeed, the Board of Appeal confirmed that designating a machine without legal capacity does not serve the purpose of the legal provisions dealing with the inventor and its designation.

Nevertheless, the Board of Appeal accepted that it is arguable that AI-generated inventions are patentable under the EPC. In such a situation, where an AI-system has generated the invention, the user or owner of the device should designate themselves as the inventor under European patent law. Therefore, the Board of Appeal concluded that European patent law was able to accommodate AI originating inventions.

The Board of Appeal rejected the appellant's argument that the public has a right to know who the inventor is and how the invention was made stating that there is no normative basis for this alleged right of the public. Moreover, the Board of Appeal

rejected the appellant's argument that Dr Thaler acquired the right to the invention as the employer of DABUS or successor in title to the invention. Indeed, the Board of Appeal stated that deriving the right to the European patent as owner and creator of the machine does not refer to a legal situation or transaction which would make Dr Thaler the successor in title of the invention.

Accordingly, the Board of Appeal dismissed the appeal.

Conclusion

The reasoning provided by the Board of Appeal in J 8/20 appears to provide a definitive answer regarding the designation of inventor for AI originating inventions. According to the Board of Appeal, an AI system cannot be designated as inventor. Instead, the user or owner of a device involved in an inventive activity should designate themselves as inventor under European patent law.

The Board of Appeal could envisage no subsequent practice or agreement which could be invoked to challenge this decision.

Nevertheless, these arguments rely on the principle that an AI system lacks legal personality – a machine cannot be a person and cannot own property. As AI systems become ever more advanced, one cannot help but feel that such a firm distinction between people and machines may become ever harder to maintain.

Author:
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According to the Board of Appeal, an AI system cannot be designated as inventor



CNIPA and EPO

Examination trends for business method related inventions

In our previous article “Computer implemented inventions (CII) in CNIPA and the EPO - recent developments of examination practice”, we briefly discussed the China National Intellectual Property Administration’s (CNIPA’s) approaches of examining CII patent applications under the proposed amendments to the China Patent Examination Guidelines and compared them to the practice adopted by the EPO. This article follows up on the topic and looks into the examination standard specifically for business method related inventions, which are also commonly implemented by computer programs, by going through some of the guidance examples and recent decisions issued by the CNIPA Patent Reexamination and Invalidation Department and the EPO Technical Board of Appeal.

Computer implemented inventions in CNIPA and the EPO - recent developments of examination practice
<https://dycip.com/computer-inventions-cnipa-epo-dec21>

Background

Business method patents were once taboo in the patent world since most jurisdictions refused to grant patent protection for innovation in pure business methods. For example, Article 52(2)(c) of the European Patent Convention explicitly excludes the patentability of the subject-matter or activities related to schemes, rules and methods for doing business as such.

In China, although methods of doing business are not written in the exhaustive list of non-patentable subject matters under Article 25(1) of the Chinese Patent Law, pure business methods are traditionally regarded as rules and methods for performing mental acts and hence non-patentable. Even if a patent claim involving business rules also contains technical elements such as hardware features, it might also risk being rejected for failing to solve a problem by utilizing the law of the nature, hence not qualified as a “technical solution” under Chinese Patent Law Article 2(2).

Nevertheless, as information technologies emerged towards the end of the last century, they have spurred innovation in various complementary fields including the commercial and business sectors. Patent offices across the world started to grant patents which relate to business practices. In 2006, the International Patent Classification (IPC) also introduced the main group G06Q for categorizing business method patents, and WIPO describes the group as “data processing systems or methods, specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes; systems or methods specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes, etc”. With tens of thousands of patent applications under this category being filed every year, the EPO and CNIPA have evolved and refined their own patent examination practices, aiming to strike a balance between providing protection, encouraging innovation, and promoting competition.

Recent CNIPA approach

In CNIPA, while the draft Examination Guidelines Amendment previously published for public consultation in August 2021 is still being finalised, the current practice concerning business method patents is prescribed by the Examination Guidelines in force which was issued in December 2019. Among other updates, the 2019 edition contains a whole new section 6 in Part II, Chapter 9 to set out the guidance for examining CII inventions, and covering specifically business method patents.

This includes the assessment of invention step for “new business new field” inventions related to, for example, AI, Internet+, big data and block chain, and characterized by patent claims containing a mixture of technical features and non-technical features. Note that by “non-technical features”, it means those intrinsic features which are not eligible for patent protection, for example, scientific discoveries, mathematical models, method of doing business, etc. Therefore, machine learning models are still considered as “non-technical features” under the patent law since

they are mathematical models in nature, even they are viewed as science and technology developments by common understanding.

Leading Patent Reexamination and Invalidation Department invalidation case

Among the top ten patent invalidation cases announced by the CNIPA Patent Reexamination and Invalidation Department in 2021, the “power bank rental method” case was given as a prototypical example for the examination standard of business method applications. The patent in the invalidation case concerns a method, a cloud server and a power bank rental terminal and targets to provide flexible charging services for renting a power bank from a mobile terminal. The rental process involves communication between the mobile terminal, a cloud server and a power bank rental terminal, and is conducted by automatically matching the technical specifications of the mobile terminal and the power banks available at the rental terminal.

The closest prior art discloses a bicycle rental management method based on mobile phone application. The method similarly requires data transmission between three parties: a mobile terminal, a server, and a rental apparatus having a bike lock. The distinguishing features lie in the application scenario. According to the closest prior art, the renting party needs to check the conditions of the bikes available for renting and select a suitable bike based on their preference. On the contrary, the rental process of the patent in dispute is completely controlled by the system consisting of the mobile terminal, the cloud server and the power bank rental terminal. User intervention is not required in selecting the power bank and in particular the renting party does not need to check the power banks in the rental terminal in order to choose the suitable one. On this basis, it was found by the Patent Reexamination and Invalidation Department decision that the above distinguishing features provide the technical effect of user convenience and a more reliable and efficient rental process. Specifically...

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the Patent Reexamination and Invalidation Department ruled that the application scenario of the claimed invention achieves reliable technical effects without excessive user participation. These technical effects are not obtained by the business rules alone, but through an integration of the business rules and the corresponding technical features, so that the respective features are mutually supporting and interacting with each other.

The decision demonstrates the principle that when judging the inventive step of an invention where the distinguishing features are business rules, the role of such business rules should not be ignored by default. Instead, the interaction between the technical features and rule features should be reviewed in order to determine whether the technical solution as a whole can solve a technical problem and bring about a technical effect through mutual support and interaction of the respective features.

Example in CNIPA Examination Guidelines

The decision seems to be consistent with the provisions in the Examination Guidelines and particular the analysis in the hypothetical example of “logistic distribution method” case which emphasized the analysis of “mutually supportive, having an interactive relationship” between non-technical features and technical features.

Specifically, the claimed method distinguishes from the prior art by the step of notifying the arrival of batch orders. The distinguishing feature is realized by introducing new logistic rules as well as modifying the data structure and protocols for the communication between the server, the logistics terminal and the user terminal. Therefore, the logistics rules and the technical implementation are functionally mutually supportive and have an interactive relationship. The claimed invention solves the technical problem of how to increase the efficiency of sending order arrival notification. Furthermore, a technical effect is recognized by CNIPA based on the enhanced user experience which is achieved by faster reception of information about the order arrival status.

Recent EPO approach

The EPO sets out the relevant examination practice in its Examination Guidelines G-VII 3.6, which is also highlighted as the “COMVIK approach” in the 2022 March version. The approach has been affirmed by the Enlarged Board of Appeal decision G 1/09 issued in 2021. The EPO Guidelines additionally provide five case examples to illustrate the COMVIK approach in accessing inventive step of mixed inventions. The first example related to “method of facilitating shopping on a mobile device” may be considered as a benchmark case as it was repeatedly cited to reflect the EPO practice in comparative study reports jointly prepared with the CNIPA and the JPO.

Example in EPO Examination Guidelines

In the “method of facilitating shopping on a mobile device” example, the distinguishing features over the prior art are: (1) allowing user to select two or more products to purchase instead of a single product only; (2) providing the user an “optimal shopping tour” for purchasing the products; and (3) determining the present optimal shopping tour based on previous optimal shopping tours stored in the cache memory.

The EPO Guidelines determines that distinguishing features (1) and (2) are business-related, hence non-technical and making no technical contribution over the prior art. Only distinguishing feature (3) makes a technical contribution and the objective technical problem is how to modify the method of the prior art to efficiently implement the business concept according to features (1) and (2).

The EPO seems to be generally reluctant to recognize any technical effect produced by business rules. In fact, all case examples discussed in the EPO Guidelines have concluded that no technical character is contributed by the business rules concerned.

TBA appeal cases

Apart from the EPO Guidelines examples, it is observed that the COMVIK approach has been widely adopted in recent Technical Board of Appeal decisions involving mixture of technical and non-technical features:

T 1259/15

The subject-matter of the application relates to a handheld device for determining the location of physical objects stored in storage containers. The closest prior art already discloses that mobile devices could be used to read tags to identify objects and locations though it fails to disclose a logical association of the physical object and the storage container in which the physical object is placed.

In the decision, the Board of Appeal considered that logically associating two items with each other and/or location information, when taken alone, does not contribute to the solution of a technical problem. The Board of Appeal also rejected the argument that a technical effect is produced through identifying the container in which a physical object is stored based on the logical association.

The only technical effect of the claimed invention recognized by the Board of Appeal is the automation of the logical association method steps using a handheld device.

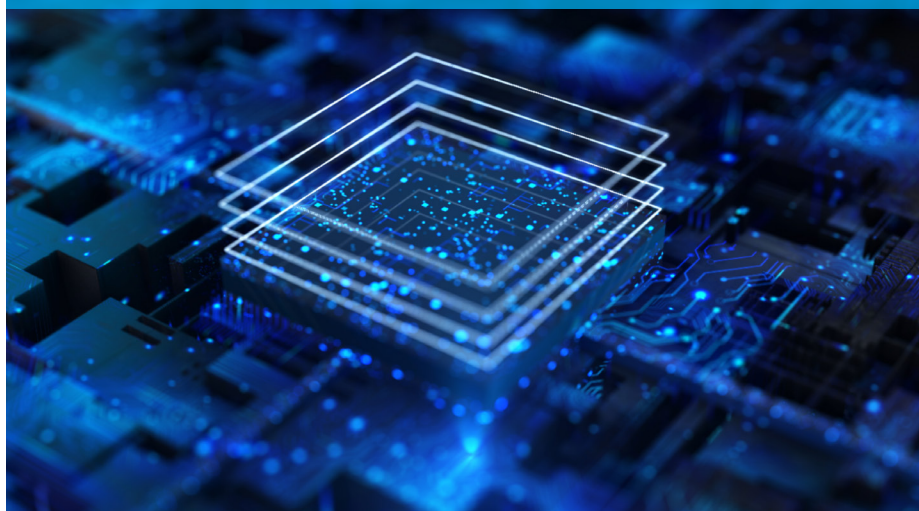
Further, the Board of Appeal referred the steps of logically associating items with each other as independent of the technical implementation of the automation process. The Board of Appeal therefore found that the non-technical features neither contribute to the solution of a technical problem as a whole and concluded that the claimed subject-matter does not involve an inventive step.

T 0658/18

The invention concerns wireless devices conducting payment and non-payment transactions, in particular an aggregated soft card on a mobile device.

The closest prior art describes a technical solution of using soft cards on a mobile device to replace physical cards. It further describes a primary component soft card and a secondary component soft card but fails to disclose the claimed process of requesting and providing a single aggregated soft card, a feature which

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was considered as business rules and non-technical by the examining division.

The Board of Appeal however disagreed with the examining division's finding and determined that the generation of an aggregated soft card as a combination of two or more electronic or virtual cards actually involves technical features such as provision of a trusted service manager (TSM) server for accessing a mapping database and provision of a link including an application identifier list. As a result, the Board of Appeal considered that it cannot decide without search results with respect to these features in hand and remitted the case to the examining division for a search and further examination.

Inevitable divergence between EPO and CNIPA?

From the above case examples, we can see that the approach of evaluating the inventive step for computer implemented inventions in the CNIPA shares many similarities with the EPO, partly because the CNIPA three-step approach and EPO problem solution approach both involve identifying the distinguishing features over the closest prior art and subsequently considering any technical contribution made by these features to the solution of a technical problem. In the case of business method inventions, those non-technical

features such as business rules forming part of the technical solution for solving a certain technical problem shall be considered when accessing inventive step.

Nevertheless, the approaches start to deviate when it comes to determining whether a non-technical feature forms part of the technical solution, or whether a technical effect is achieved by the non-technical feature. To assist this assessment, EPO Guidelines G-II 3.3 provides a list of technical applications which serves as a reference for how non-technical features, particularly mathematical models, can produce a technical effect. Nevertheless, the list of technical applications does not seem to be relevant to business methods.

The CNIPA and EPO Guidelines examples and real life cases discussed above more or less involve adopting new business rules. However, arguments based on technical effects of user convenience or enhanced user experience which are relied by the CNIPA Guidelines example are unlikely to have a firm position before the EPO.

In the context of determining whether a non-technical feature contributes to a technical effect, the EPO COMVIK approach therefore appears to be stricter than the CNIPA approach based on "mutually supportive

and interactive relationship" between non-technical and technical features, despite the additional hurdle in CNIPA requiring the invention as a whole to be a "technical solution" utilizing the laws of nature.

While a more innovative approach has been taken by the CNIPA to address the issues of mixed invention, the practice regarding the "mutually supportive, having an interactive relationship" criteria is to be established through the final release of the 2021 Examination Guidelines amendments and forthcoming Patent Reexamination and Invalidation Department decisions. On the other hand, the EPO is more inclined on tackling the problem by developing from a more traditional approach based on a 2002 decision. There may be question whether this approach is sufficiently flexible to provide appropriate protection for innovations in those fast developing IT business and technical fields.

Conclusions

The takeaways from these observations are that when preparing patent applications relating to business method innovation, the applicant may consider describing the non-technical features, namely new business rules, from the perspective of mutually supportive effects and interactive relationship with technical features for implementing the rules.

In addition, the business rule elements described in the specification and recited in the claims may need to be formulated as changes to the technical features such as the hardware, signals or data structure as a result of the implementation of the business rules, in order to support arguments for confronting the hurdles under the EPO COMVIK approach.

A patent drafting practice with the CNIPA and EPO approaches in mind may be beneficial as the two jurisdictions move forward on substantive patent law harmonization in the long run.

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