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Driven by Technology: Patenting AI Before the European Patent Office (Part IV)

In this fourth and final article of our series on artificial intelligence (AI) inventions at the European Patent Office (EPO), we look at computer-implemented simulation methods and how knowing the EPO's practice in relation to these methods can help in assessing the inventive step of AI inventions.

1. Introduction

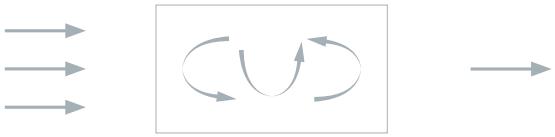
As outlined in the first and third articles of the present series,[1] the EPO applies the COMVIK approach to assess the patentability of computer-implemented inventions, including those relating to AI. Under this approach, features that are deemed not to have technical character, as is often the case for features related to AI, are disregarded for the question of inventive step.

However, the Guidelines for Examination in the EPO state that mathematical methods, of which AI is a sub-group,[2] may contribute to the technical character of an invention, i.e., contribute to producing a technical effect that serves a technical purpose, by their application to a field of technology.[3]

Moreover, the Guidelines for Examination[4] state that computer-implemented methods of simulation are another sub-group of mathematical methods and should also be examined according to the COMVIK approach.

Since both methods of using AI and simulation are treated as mathematical methods and examined in the same way, inventive step of AI inventions may be argued by analogy with simulation techniques. In this respect, the recent decision G 1/19 of the Enlarged Board of Appeal of the EPO, which relates to simulations of the movement of a crowd of pedestrians, plays a prominent role.

The remainder of this article discusses possible implications of G 1/19 on drafting patent applications related to AI to be filed with the EPO. In our discussion, we will refer to a simulator as schematically represented in G 1/19, considering the analogy between a simulator engine and an AI engine, both of which are based on mathematical models.[5]



Input data | Simulator engine processing and, by analogy, AI engine processing | Output result

2. Technical effects at the input to a computer-implemented process

Focusing initially on the input to a computer-implemented designer simulation, G 1/19 provides a first hint as to how technical character may be established, noting that technical input may consist of a measurement.[6] In this decision, the Enlarged Board held that measurements, even when carried out by indirect means involving significant computing efforts, are related to physical reality and thus of a technical nature, regardless of what use is made of the results.[7]

[1] Michele Baccelli, "Driven by Technology: Patenting AI Before the European Patent Office (Part I)", Hoffmann Eitle Quarterly, June 2022, pp. 2-5; Stephanie Rupp, Rifat Camurdan, Michele Baccelli, "Driven by Technology: Patenting AI Before the European Patent Office (Part III)", Hoffmann Eitle Quarterly, December 2022, pp. 2-5.
[2] Guidelines for Examination in the European Patent Office (March 2023 edition), section G-II, 3.3.1.
[3] Ibid., G-II, 3.3.
[4] Ibid., G-II, 3.3.2.
[5] See G 1/19, reasons 84, and part II of the present series of articles discussing a related representation for AI.
[6] G 1/19, reasons 85.
[7] Ibid., reasons 99.

As such, one potential way forward when faced with a non-technical subject-matter objection may be to argue that the input data and how such data is input to the computer-implemented process contributes to a technical effect, e.g., by improving a measurement technique.

In T 438/14, the Board of Appeal held that the claimed subject-matter involved an inventive step, due in part to the technical contribution made by inputting data to a simulation.

The method in question involved determining an area of a surface in which there is an increased risk of condensation by imaging a surface with an infrared (IR) camera. Different conditions were simulated in order to calculate the resulting risk of condensation by manually inputting different values for air temperature and humidity into the IR camera.

The Board held that the feature of "*simulating different conditions, by imaging the surface using different values for the air temperature and humidity*" did not relate to a non-technical mental act because it implied, inter alia, technical means for manually inputting values to the camera. In other words, the mental act would be limited to the selection of the actual values to be input, with the claim being however concerned with what is done after the selection is made.

The feature of simulating different conditions was thus held to contribute to solving the problem of enabling indication of the risk of condensation on a surface for various environmental conditions which might occur during the service life thereof.[8] We believe it may be inferred from this reasoning that the values input to the computer contribute to creating a link between the simulation and the real physical item that is simulated, without necessarily claiming the physical item, especially within the context of solving a technical problem as in the present case.

In another example, EPO Board of Appeal decision T 1234/17 concerns an invention related to the customization of a piece of footwear. The novel aspects of the method lay in applying a model of human physiology, by a sensor data analysis module, to associate a time series of acceleration vectors measured by an accelerometer with one of multiple categories of human gait and customizing the footwear using the determined gait characteristics.

While the refusal of the application for lack of inventive step was ultimately upheld by the Board in question, the Board considered that an invention may lie in the improvement of the measurement technique itself, which involves technical considerations about the input data or the sensors.[9] In this regard, the Board noted that the claim only specified that the data "*includes a time series of acceleration vectors*" and that this data is "*analyzed*". Also, the Board was not convinced that the overall simulation would contribute to the technical solution on grounds that "*customising footwear depending on the model of human physiology, that is, the type of human gait, does not contribute to inventive step, but is a non-technical idea*".[10]

As such, the Board concluded that there were no further details that could constitute such technical considerations about the input data or the sensors in order to distinguish from previous decisions[11] in which such argumentation had been accepted. Hence, we may derive from this decision that, while measurements are considered to be of a technical nature as they are related to physical reality in line with G 1/19, this may not be sufficient to also support inventive step, which requires the features making a technical contribution to provide a technical effect.

[8] T 438/14, reasons 1.6: "A mental act, if there were one, would be limited to the selection of suitable values [...]. However, step f) [i.e., "simulating ... using different values"] implies technical means for manually entering values and for calculating [...]. Method step f) therefore implies technical means and does not represent a mental act as such".

[9] T 1234/17, reasons 2.12 and 2.13.

[10] See T 1234/17, r. 2.10.

[11] See, e.g., T 2079/10.

3. How can the computer-implemented process itself be technical?

Turning to the computer-implemented process itself, the Enlarged Board in G 1/19 also upheld existing case law that an algorithm may contribute to the technical character of an invention if it is particularly suitable to be run on a computer in that its design was motivated by technical considerations relating to the internal functioning of the computer.[12]

Thus, not all technical considerations provide basis for arguing in favour of technical character. As discussed by the Enlarged Board in G 1/19,[13] the technical considerations should relate to implementation of the method, and not to the system being modelled or simulated thereby.

The decision in T 2594/17 illustrates this distinction. The claimed invention in this case related to a system that rendered and performed simulated testing of a 3D virtual weldment and allowed inspection of the 3D virtual weldment on a display device. In this case, the Board noted that the 3D virtual weldment did not correspond to any 'real life' weldment and did not allow potentially damaging or destructive 'real life' testing to be avoided through use of the simulation.[14]

Referring to G 1/19, the Board held that it is not a sufficient condition that a simulation is based on technical principles underlying the simulated system or process.[15]

The Board concluded that, in this context, technical aspects relating to the weldment and how weldment testing is performed were not relevant to the claimed invention.[16] In fact, the Board held that the type(s) of tests to be implemented would be given to the skilled person as a constraint for implementation.[17]

Turning to the computer-implemented simulation itself, the Board noted that the underlying application describes what the rendering and the analysis engines of the claimed system do but does not provide any information as to how they do it. That is, the Board held that the underlying application did not provide any information about technical constraints or considerations regarding the implementation of these engines.[18]

This led in turn to the Board's conclusion that the skilled person would be tasked with implementing display and processing of images representing 3D weldments, their testing and inspection, which could be carried out using common general knowledge in an obvious manner and, thus, a finding of lack of inventive step. In other words, the invention at issue apparently relates to a simulation aimed at visually representing how a system works for the purposes of training personnel, wherein no technical purpose is acknowledged and wherein the simulation requires knowledge of the model underlying the system rather than technical knowledge for the realisation of the simulation tool.

This analysis of a simulation-based method highlights the importance for mathematical methods in general of distinguishing between the technical considerations described by the information being processed and the technical considerations of how the method is implemented.

[12] G 1/19, reasons 112.
[13] Ibid., reasons 125 and 126.
[14] T 2594/17, reasons 3.2.3.
[15] Ibid., reasons 3.2.10.
[16] Ibid., reasons 3.2.4 and 3.2.5.
[17] Ibid., reasons 3.3.3.
[18] Ibid., reasons 3.3.2 to 3.3.5.

4. Limiting a claim to a technical purpose

In addition, the Guidelines provide that technical character may be conferred to claimed features of a mathematical method where these features provide a technical effect that serves a technical purpose.[19]

This requires that a specific technical purpose limits the claim in question, which may be achieved by specifying how the input and the output of a sequence of mathematical steps relate to the technical purpose so that the mathematical method is causally linked to a technical effect.

Decision G 1/19 provides guidance on limiting a claim to a technical purpose. Namely, the Enlarged Board reasoned that, if a claimed process, e.g., a simulation or an AI algorithm, results in a set of numerical values, it depends on the further use of such data whether a resulting technical effect (and the corresponding features) can be considered in the assessment of inventive step.[20] Moreover, the Enlarged Board reasoned that avoiding a need to build certain prototypes is not a technical effect because the decision to build or not to build a prototype is a business decision made by humans.[21]

The above line of reasoning seems also to be reflected in the recent Guidelines for Examination, providing that "*if the claim also encompasses non-technical uses of the simulation results (such as gaining scientific knowledge about a technical or natural system), the potential technical effect is not achieved over substantially the whole scope of the claim and therefore cannot be relied on in the assessment of inventive step*".[22]

As an example of the above points, in its recent decision T 1035/18, Board 3.5.01 considered that whether the simulation described in the underlying application achieves a technical effect (and thus corresponding simulation-related features must be considered when assessing inventive step) depends on the further use of numerical data provided by the simulation.[23] However, the Board considered that the claimed (simulation) method did not have an implied technical use which could serve as basis for an implied technical effect.[24]

More specifically, the application underlying this decision relates to methods for estimating the net solar energy production of airborne photovoltaic systems. Simply put, an amount of electrical energy is predicted based on simulations of a flight path. Based on the predicted amount of electrical energy, corresponding fuel savings are estimated.

The applicant argued that the estimated fuel savings would result in more precise predictions of an optimal amount of fuel which an aircraft needs to traverse a flight path more efficiently.[25] However, the Board held that refuelling would occur only as a result of a human decision, and that estimated fuel savings could also be used for business decisions. The Board therefore considered that the claimed estimating of fuel savings did not have an implied technical use that could form the basis for an implied technical effect.[26] In other words, the Board does not appear to have been satisfied that the claim was limited to a technical purpose because it encompassed methods for making business decisions as a function of certain simulated parameters.

[19] Guidelines for Examination, G-II, 3.3.
[20] G 1/19, reasons 124.
[21] Ibid., reasons 123.
[22] Guidelines for Examination, G-II, 3.3.2.
[23] T 1035/18, reasons 2.7.
[24] Ibid., reasons 2.11.
[25] Ibid., reasons 2.10.
[26] Ibid., section 2.11.

Similarly, in T 3226/19 the Board reasoned that none of the features of a method for estimating an opportunity (used in planning of oil drilling) in an (oil) reservoir system restricted the claimed method to a further technical use of the estimated opportunity. Moreover, according to the Board, even if the ultimate goal of the estimation was planning an oil drilling process, any technical decision regarding the drilling process would be taken only indirectly by human experts possibly based also on non-technical business criteria.[27]

It is thus advisable to discuss in an application to be filed with the EPO how the output data provided by an AI algorithm is related to a technical effect without human decision-making.

5. Conclusions

From the above, some indications can be derived for drafting and prosecuting inventions relating to simulation or AI. Namely, the input referring to physical reality, claimed and explained in the description, may help to confer technicality; however, it is highly recommended to specify in both the claims and the description a technical purpose or application for the invention, and/or to explain and claim how a specific technical problem is solved, as the input data alone may not always suffice to render the claim technical.

Similarly, in order to increase the chances of the claim being accepted as technical, it is highly advisable to specify the technical considerations required to realise a simulator or an AI device and/or how a specific model has been chosen or adapted for a specific application/purpose.

Finally, the application should specify how the output data may be used to achieve a technical effect related to a technical purpose without requiring human decisions.

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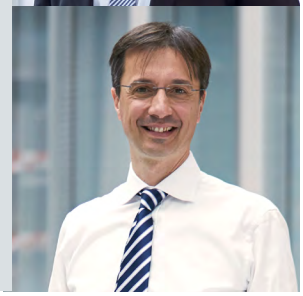

[27] T 3226/19, reasons 4.3.

Pre-published Clinical Trials: A Sudden Death for Second Medical Use Claims?

The EPO Boards of Appeal issued numerous decisions in the past on the patentability of second medical use claims in view of clinical trial reports as prior art. This article reviews selected recent decisions and highlights relevant aspects that have been considered by the Boards in their inventive step analyses.

Applicants often face the difficult situation that an application should be filed before any results of a clinical study become prior art but at the same time should plausibly demonstrate that the therapeutic effect is obtained. In view of the new EU Clinical Trials Regulation, which requires publication of all information relating to the clinical trial, this issue is even more pertinent than in the past.[1] In this regard, the question arises: When is a claimed second medical use obvious in view of a clinical trial report? The Boards' jurisprudence follows the established principle that obviousness requires a "*reasonable expectation of success*", wherein the therapeutic efficacy can be predicted with reasonable certainty based on the available facts and evidence.

Inventive step denied

The EPO Boards of Appeal found in several decisions that the report or announcement of a clinical trial, even if published without any results or data, can be detrimental for inventive step of a second medical use claim.

In the landmark decision T 239/16, the Board held that the mere fact that an active agent is being tested in a clinical study leads to an expectation of success, as the approval of clinical studies is based on successful preclinical testing and ethical considerations requiring a risk-benefit evaluation. The principle of "*dissuasion*" was brought up: A reasonable expectation of successful treatment was assumed, unless there was evidence to the contrary in the prior art that prevented or dissuaded the skilled person from pursuing the claimed subject matter.

In the case at hand, the drug zoledronic acid had been successfully tested in a **suitable animal** model. Moreover, zoledronic acid belonged to an **established class of drugs** for the treatment of osteoporosis. Even though the Board acknowledged that there was residual doubt as to whether the therapeutic effect would actually be obtained, they found that such doubt would not diminish the expectation of success to a mere hope to succeed. In view of these considerations, the Board denied inventive step. Similar conclusions were drawn in T 96/20[2] and T 1123/16.

The dissuasion principle of T 239/16 was further refined in T 2963/19, where the Board clarified that a report on a (phase III) clinical trial *per se* would not provide the skilled person with a reasonable expectation of success that the claimed treatment would be safe and effective; the outcome of a clinical trial is not certain and many studies fail to establish a therapeutic efficacy or reveal serious adverse effects of a particular dosage regimen. The considerations regarding the expected success were hence closely linked to the further facts and circumstances of each case, as in the preceding decision T 239/16. In the case at hand, the patent and the prior art both had the same level of disclosure, i.e., an outline of the clinical study without experimental results. Based on additional prior art reports on beneficial treatment with regimens similar to the claimed one, the Board found the claimed triple dosage regimen plausible, but also obvious.

[1] See the next article in the present issue of the HOFFMANN EITLE Quarterly: Irene Martin Badajoz and Boris Tchitchanov, "The EU Clinical Trials Regulation: Implications of the New Transparency Rules on Patenting".

[2] See Adam Lacy, "Difficult Times ahead for Establishing Inventive Step of Medical Use Claims at the EPO", HOFFMANN EITLE Quarterly, September 2021, pp. 5-6.

In T 99/19, the appellant (patent proprietor) contended that a prejudice existed in the art against the claimed once-daily administration, which was the only feature distinguishing the claimed subject matter from the clinical trial report. However, the Board concluded that the established strict standard for demonstrating an alleged prejudice at the priority date was not met by any of the evidence relied on, which included several expert declarations. The Board further found that the prior art did not provide any disincentive against once-daily dosing and therefore denied an inventive step.

Inventive step acknowledged

Two recent decisions highlight important considerations of the Boards where the particular circumstances and facts did not give rise to a reasonable expectation of success.

In T 1732/18, inventive step was acknowledged for a once-daily dosage regimen of rivaroxaban in treating thromboembolic disorders. The closest prior art was a phase I clinical study establishing safety of the compound in healthy subjects for the claimed and other dosage regimes. While the Board acknowledged that the person skilled in the art would have had a general expectation that the drug could provide clinical efficacy for this indication and that the skilled person would have made the transition from phase I to phase II clinical testing, they denied that the skilled person would have had an incentive and reasonable expectation of clinical success regarding the once-daily regimen as claimed. Important aspects were that **safety and efficacy had not been shown in patients** for rivaroxaban or for the class of direct-acting oral factor Xa inhibitors in general. The Board emphasized that the case at hand differed from the typical situation in other dosage regimen cases, where development is based on established therapeutic uses of the drugs concerned.

There was no evidence of **threshold values** or potential **correlations** of the thrombin generation assays used in the secondary document **with clinical efficacy and safety** in patients. Moreover, due to the known short plasma concentration half-life of rivaroxaban, the person skilled in the art would have expected that twice- or thrice-daily dosing, or else the use of a sustained-release formulation, would be required to maintain efficacy and safety. Hence, the Board concluded that there was no reasonable expectation of success for the claimed dosage regimen using a rapid-release formulation of the drug.

In the examination appeal T 108/21, the Board acknowledged plausibility of the effective therapy of RRMS with an oral daily dose of 0.5 mg fingolimod, based on the application's data from an animal (rat) model, and pharmacokinetic characteristics of fingolimod discussed in an expert declaration. On inventive step, the closest prior art disclosed a successful phase II trial with a dose of 1.25 mg fingolimod, followed by the announcement of a phase III trial using oral daily doses of 0.5 mg and 1.25 mg. According to the Board, this announcement would have provided the skilled person with a reasonable expectation that the claimed daily dose of 0.5 mg solves the objective technical problem, unless there was a dissuasion in the prior art. The Board found such dissuasion in a research article postulating that a threshold of lymphocyte reduction of about 70% was required to see efficacy in an SJL mouse model, combined with further prior art reporting that an oral daily dose of 0.5 mg fingolimod achieved lymphocyte reduction of less than 70% in humans. Notably, the Board seems not to have considered that an oral daily dose corresponding to 1.25 mg (known to be effective from the phase II trial) had failed to reach that threshold in humans. The Board also did not consider any of the prior art filed with numerous third-party observations during the appeal (see r. 3). Currently, opposition proceedings with 16 opponents are ongoing, and it remains to be seen whether the evaluation of the available facts and evidence will lead to a different outcome.

Factors to be considered in the assessment inventive step in view of a clinical trial disclosure:

- Compound or class of compounds known to be effective
- Correlation between preclinical data or particular parameters and therapeutic efficacy and/or safety
- Threshold values for therapeutic efficacy
- Established animal models
- Successful clinical studies in patients
- Serious side effects
- Risk factors of patient group

Conclusions

The assessment of the plausibility of a second medical use depends on the available facts and evidence of each case. As a common ground, the Boards take into account whether the compound or class of compounds is already known in the treatment or if there are established correlations between preclinical data or animal models and the therapeutic effect in patients. Safety aspects are also considered by the Boards and may act in favor of inventive step. Generally, it is advisable to file a patent application relating to a second medical use as early as possible, but to ensure that sufficient data is included that makes the claimed treatment at least plausible. The much-awaited outcome and reasoning of G 2/21 on whether post-published data may be considered in the evaluation of patentability will certainly have an impact on these considerations.

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The EU Clinical Trials Regulation: Implications of the New Transparency Rules on Patenting

Clinical trials (CTs) are scientifically controlled studies in humans to establish or confirm safety and effectiveness of investigational medicinal products (IMP). CTs can be particularly important for obtaining patent protection for new medical uses of known pharmaceuticals.

The conduct of CTs in the European Union (EU) was previously governed by the Clinical Trials Directive (CTD).[1] A new EU Clinical Trials Regulation (CTR) is now in force, aiming at increasing transparency of trial information in the EU.[2]

1. All trial-related documents will be published by default under the new transparency rules

New disclosure rules under the CTR require publication of much more comprehensive information than previously under the CTD:

	Clinical Trials Directive (CTD) 2001/20/EC[3]	Clinical Trials Regulation (CTR)(EU) No. 536/2014[4]
Documents published	Clinical data (clinical reports; individual patient data)	All CT-related information (including protocol, investigator brochure, IMP dossier[5] , subject information sheet, assessment reports and decision on trial conduct, summary of results)
Applicable to	CT applications submitted before January 31, 2022 (transitional provisions apply for trials approved or applied for before January 31, 2023)	All CT applications submitted from January 31, 2023 onwards; all ongoing and new trials from January 31, 2025 onwards

To obtain authorisation for a CT conducted in the EU, an application dossier must be submitted via an online EU database (the Clinical Trials Information System, CTIS).

All information therein will be publicly accessible from the date of the decision on conduct of the CT, unless confidentiality is justified (e.g., for protecting personal data; or for protecting commercially confidential information but only if there is no overriding public interest in disclosure). Such public interest may prevail in particular ad hoc situations (e.g., where very serious safety incidents have occurred in the trial).

2. Deferring and/or redacting disclosure of documents; publication timelines

To balance the public interest in disclosure with the legitimate economic interests of sponsors in keeping information confidential, deferral rules are established based on grouping clinical trials into categories: 1 (Phase I, Bioequivalence and Bioavailability trials and bio-similarity trials); 2 (Phase II and II trials); and 3 (Phase IV and low-intervention trials).

[1] Directive 2001/20/EC of the European Parliament and of the Council of April 4, 2001.
[2] Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014.
[3] European Medicines Agency policy on publication of clinical data for medicinal products for human use (POLICY/0070, EMA/144064/2019; last updated March 21, 2019).
[4] Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014" (October 2, 2015).
[5] The Investigational Medicinal Product Dossier is a regularly updated, detailed technical and scientific description of the investigational medicinal product; the sections on Safety and Efficacy therein provide extensive non-clinical and clinical trial data, plans for future trials and details of the current risk benefit assessment, including details relevant not only to the trial applied for but for any anticipated trials, those in other the indications, pharmaceutical forms and routes of administration that may be developed further in the future. The Investigator Brochure contains extensive detail on the pre-clinical and clinical testing and development of the IMP as well as further lines of investigation for future development.

Deferral of publication and/or redaction of documents containing commercially confidential information may be granted upon justified request submitted with the CT application, in the absence of overriding public interest, and depending on the category of the trial.[6] For instance, deferral of publication of the protocol for up to 7 years after the end of the trial may be available for category 1 trials, but only for up to 12 months for category 3 trials.

The graph below shows a simplified timeline highlighting the earliest possible default publication times of trial-related documents (and some potentially available deferral periods) under the CTR, and the process for obtaining marketing authorisation (MA).

3. The published documents can be relevant to patentability

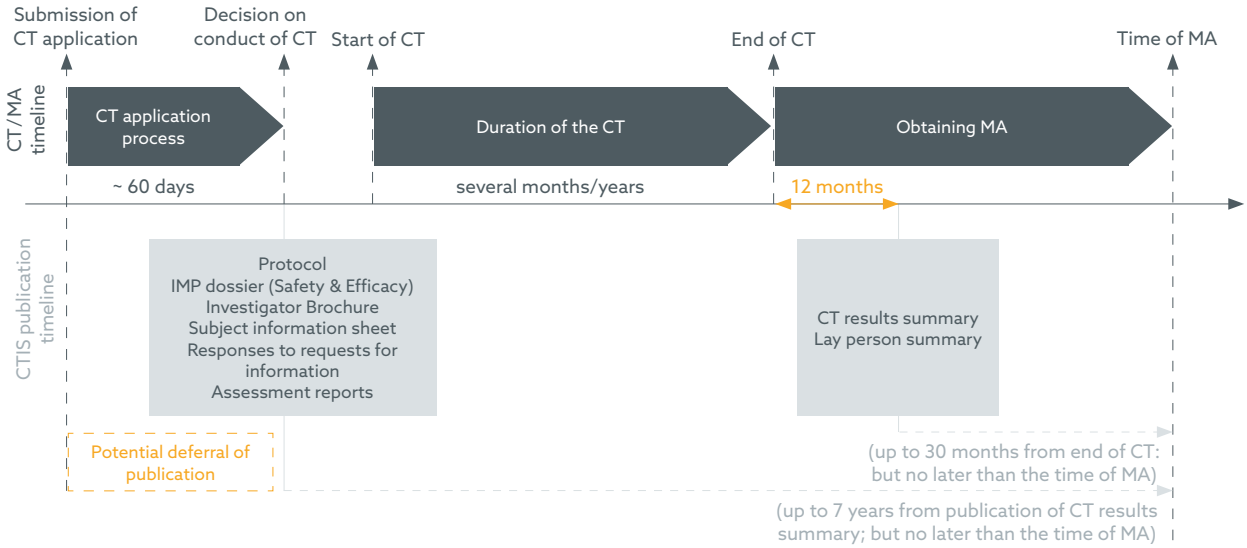
Transparency of CTs will be the rule. Comprehensive trial-related documents will become prior art, which may be used to challenge the patentability of later-filed patent applications or patents.

Multiple decisions of the EPO Boards of Appeal have assessed the relevance of clinical trial reviews, patient information disclosures, protocols, announcements and reports as prior art cited against medical use claims. In some cases, depending on the facts and circumstances, the EPO has considered that CT-related prior art disclosures (e.g., a protocol or a clinical trial announcement) do not automatically mean that the outcome is predictable and that an inventive step must be acknowledged (e.g., T 1806/18). But in many other cases, such disclosures turned out to be detrimental to inventive step (e.g., T 1853/16, T 239/16, T 2506/12, and T 96/20).[7]

Early disclosure of any CT-related documents under the new transparency rules, especially if no deferral is requested or granted, will thus be an additional hurdle for patentability of later-filed patent applications and patents.

4. IP strategy considerations

For innovative pharmaceutical companies (i.e., patent applicants and/or CT sponsors), the further potentially relevant documents that may become public under the new CTR will make the "old" dilemma – when to file the patent application – even more pertinent. The situation is complex, so it is important to define the IP strategy well before submitting the CT application. All this requires early and efficient coordination between expert IP and regulatory teams.



[6] Draft guidance document on how to approach the protection of personal data and commercially confidential information in documents uploaded and published in the Clinical Trial Information System (CTIS) (EMA/212507/2021; First published: April 8, 2022).

[7] See the previous article in the present issue of the HOFFMANN EITLE Quarterly: Claudia Unsin, "Pre-published Clinical Trials: A Sudden Death for Second Medical Use Claims?".

On balance, even more than in the past, it is advisable to file a patent application as early as possible, ideally before submitting the CT application. This would avoid the risk that CT-related documents become prior art. But the application should make the claimed effect plausible, otherwise the claims might be insufficiently disclosed or lack inventive step (which will be case-dependent;[8,9] see also pending referral G 2/21). So, as much pre-clinical data and theoretical explanations of the underlying mechanisms of action as possible should be included in the patent application.

Requesting deferral of publication and/or redaction of CT-related documents should be considered when submitting the CT application. Re-evaluation of the strategy may become necessary once the regulatory authorities issue the decision on the CT, depending on whether deferral of publication has been granted or not. For instance, if no relevant CT-related documents will be immediately published with the decision on the trial, and if the data in the patent application is scarce, it might be prudent to withdraw the already-filed application and file a new one as the first application, if and when further (pre-)clinical data become available over the course of the trial.[10]

If a patent application has not been filed before submitting the CT application, this may be done at a later stage, e.g., before the CT results are available, or at the end of the CT but before publication of the results (which will take place 12 to 30 months after the end of the trial in the EU, see above timeline). This strategy would be particularly advantageous if deferral of publication of the initial CT application documents has been granted, allowing the inclusion of solid (clinical) evidence supporting the claimed effects in the patent application and a later expiry of patents granted thereon. But it would involve a higher risk of disclosures by third parties and/or documents from the CT application becoming prior art (e.g., if no deferral was requested or granted in the EU, or if trial-related documents are published in other jurisdictions).

As seen from the decisions cited above, trial-related disclosures, and not patent documents, are often the most relevant prior art. For third parties (especially generic manufacturers), the CT Regulation opens up a new source of potentially relevant prior art for challenging competitors' patents and of information on the sponsor's activities.

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[8] Kallenbach, L., Vallazza, M. Are the new clinical trial transparency rules incompatible with the patentability requirements in Europe? Nat Biotechnol 36, 928–930 (2018); https://doi.org/10.1038/nbt.4265.

[9] Kallenbach, L., Vallazza, M. Gefährdet die neue Transparenz bei klinischen Studien den Patentschutz von Innovationen? EPI Information 04/2017, p. 36-43.

[10] But beware of the requirements of Art. 87(4) EPC.

New Administrative Procedures for Invalidity and Revocation of Italian Trademark Registrations

In Italy, new administrative procedures for invalidity and revocation of registered trademarks have recently come into force, making it possible to bring these actions before the Italian Patent and Trademark Office (UIBM) and not only before the ordinary courts as was previously the case. These new procedures are faster and cheaper than litigation in the Italian Courts. However, the more accessible administrative procedures will expose Italian trademark registrations to a higher risk of challenge. Trademark owners should therefore consider adopting preventive strategies. This article summarizes the main procedural aspects and provides practical advice.

Introduction

The new administrative procedures entered into force pursuant to the publication on 29 November 2022 (Official Gazette n. 279) of the Decree 19 July 2022 N. 180 of Ministry of Economic Development (now Ministry of Enterprises and Made in Italy). The decree implements the provisions of EU Directive 2015/2436, which required the entry into force of administrative invalidity and revocation actions for trademarks by January 14, 2023 in all EU member states.

Grounds of invalidity actions[1]

According to the new administrative procedures, invalidity actions may be based on the following "*absolute*" grounds:

- the trademark does not meet the requirements of distinctiveness and representation,[2] the trademark consists of non-registrable shapes or characteristics,[3] the trademark consists of coats of arms or emblems protected by international conventions;[4]
- the trademark lacks distinctive character;[5]
- the trademark is contrary to law or to accepted principles of morality or it is deceptive;[6]
- the trademark is excluded from registration pursuant to the EU law, national law or to international agreements to which the EU or the State is party, providing protection for designations of origin and geographical indications, traditional terms for wines, traditional specialties guaranteed, or the denominations of plant varieties. That is, earlier designations of origin or geographical indications may prevent the registration of a later trademark if the designation of origin or the geographical indication entitles the person authorised under the relevant law to exercise the rights arising therefrom and to prohibit the use of a subsequent trademark;[7]

and on the following "*relative*" grounds:

- the trademark is identical or similar to an earlier Italian or EU trademark registered for identical or similar products or services;[8]

[1] Art. 184 – bis (3) of the Italian Code of Industrial Property.
[2] Art. 7 of the Italian Code of Industrial Property.
[3] Art. 9 of the Italian Code of Industrial Property.
[4] Art. 10 (1) of the Italian Code of Industrial Property.
[5] Art. 13 (1) (a) (b), (2), (3) of the Italian Code of Industrial Property.
[6] Art. 14 (1) (a) (b) of the Italian Code of Industrial Property.
[7] Art. 14 (1) (c-bis) (c-ter) (c-quater) (c-quinquies) and (1-bis) of the Italian Code of Industrial Property.
[8] Art 12 (1) (c), (d) of the Italian Code of Industrial Property.

- the trademark is identical or similar to an earlier Italian or EU registered trademark irrespective of whether the good or services for which it is applied are identical, similar or not similar to those for which the earlier trademark is protected, where the earlier trademark has a reputation and where the use without due cause of the trademark applied for would take unfair advantage of, or would be detrimental to, the distinctive character or the repute of the same;[9]
- the trademark is identical or similar to an earlier trademark which is well known pursuant to article 6bis of the Paris Convention;[10]
- the trademark was filed by the agent or representative without the consent of the owner or without a justifiable reason.[11]

Other prior rights can be invoked only in court, such as i) unregistered trademarks, company name, trade name, domain name or other distinctive sign adopted by others;[12] ii) copyright, industrial property right or other exclusive right of third parties;[13] iii) rights to names, portraits, and well-known signs[14]; or iv) bad faith.[15]

Grounds of revocation actions[16]

Administrative revocation actions may be based on the following grounds:

- the trademark has become a common name in trade;[17]
- the trademark has become misleading, or contrary to law or to accepted principles of morality;[18]
- the trademark has not been used in the last 5 years after registration for the claimed goods and services unless the non-use is justified by a legitimate reason.[19]

Persons entitled to bring administrative actions[20]

- any interested party, in cases of invalidity actions based on "absolute" grounds;
- the owner of the prior trademark in the case of invalidity actions based on "relative" grounds, or the person entitled to exercise the rights conferred by a designation of origin and geographical indication in the case of invalidity actions based thereon;
- the owner of the trademark concerned, in case of a trademark filed by an agent or representative without the consent of the owner;
- any interested party, in cases of revocation actions.

Time limits

There is no time limit for filing an application for revocation. However, an application for revocation for non-use is only admissible if the Italian trademark has been registered for more than 5 years at the date of filing of the request.[21]

There is no time limit for filing an application for invalidity. However, owners of earlier rights are no longer entitled to file an application for invalidity on relative grounds if they tolerated the use of the later trademark for a period of five consecutive years (limitation as a consequence of acquiescence).[22]

[9] Art. 12 (1) (e) of the Italian Code of Industrial Property.
[10] Art. 12 (1) (f) of the Italian Code of Industrial Property.
[11] Art 184-bis (3) (c) of the Italian Code of Industrial Property.
[12] Art. 12 (1) (a) and (b) of the Italian Code of Industrial Property.
[13] Art. 14 (1) (c) of the Italian Code of Industrial Property.
[14] Art. 8 of the Italian Code of Industrial Property.
[15] Art. 19 (2) of the Italian Code of Industrial Property.
[16] Art. 184 - bis (2) of the Italian Code of Industrial Property.
[17] Art. 13 (4) of the Italian Code of Industrial Property.
[18] Art. 14 (2) (a) and (b) of the Italian Code of Industrial Property.
[19] Art. 24 of the Italian Code of Industrial Property.
[20] Art. 184 - ter of the Italian Code of Industrial Property.
[21] Art 63 - quarter (3) (f) of Decree of the Minister of Economic Development No 33 of 13 January 2010 and following amendments.
[22] Art. 28 of the Italian Code of Industrial Property.

Procedural aspects[23]

It will not be possible to combine invalidity and revocation applications within a single proceeding, nor to challenge different registrations of the same owner with a single application.

The application of invalidation and revocation must be complete upon filing since the subsequent filing of documents is not allowed.

When the action is found admissible, the Office informs the owner of the challenged trademark by sending a notification to both parties providing them with the terms of the cooling-off period, during which the parties can solve the matter amicably. The cooling-off period can be extended by agreement of both parties up to a maximum of 12 months from the notification date. If the cooling-off period ends without an agreement between the parties, the owner of the challenged trademark has to file arguments within a time limit set by the Office. Within the same time limit, the owner may also request proof of use of the earlier trademark if the challenge is based on an earlier trademark registered for at least 5 years.

The Office then provides the applicant with the owner's arguments and request for proof of use (if any) and sets the deadline for submitting counterarguments and proof of genuine use (if required).

Pursuant to the exchange of arguments between the parties, the Office issues its decision. The decision is issued within 24 months[24] from the date of the filing if the proceedings have not been suspended. The decision can be appealed to the Board of Appeals (*Commissione dei Ricorsi*) and after that to the Italian Supreme Court (*Corte di Cassazione*).

The final decision will have effect *erga omnes* and will have different effects depending on the action at stake. Namely, invalidity will take effect from the date of registration of the contested trademark, while revocation will take effect from the filing of the revocation action or from an earlier date on which one of the grounds for revocation occurred (if requested by the applicant).

Practical advice

The administrative procedures do not replace legal actions but should be seen as an additional tool. An applicant should decide on a case-by-case basis whether administrative or legal action should be taken.

The legal action will for example remain the only way to claim damages or to invoke prior rights that can be invoked only in front of the court, as mentioned above.

On the other hand, administrative invalidity and revocation actions may be particularly useful, in terms of reducing costs and time, to remove trademarks that prevent the registration or use of a desired trademark. This reasonably increases the risk of cancellation actions.

In the light of the above, trademark owners should consider developing defensive measures aimed at assessing and possibly preventing the risk of invalidity or revocation of their trademarks.

As possible defensive strategies, trademark owners should consider:

- keeping record of the evidence of use of their trademarks, to be able to prove actual use in case of challenge for non-use;
- analysing both the actual use of trademarks and any restyling thereof, to identify possible risks of revocation for non-use and develop further defensive strategies if necessary; and
- conducting availability searches before filing trademark applications, to assess the risk of challenges on absolute grounds (lack of distinctiveness, unlawfulness, immorality and/or deceptiveness) and/or on relative grounds (presence of confusingly similar prior trademark applications or registrations), bearing in mind that the same absolute and/or relative grounds mentioned above, if retrieved in this first search, may stands in the way of the trademark either before registration is obtained due to an ex officio refusal (absolute grounds) or opposition (relative grounds), or after registration due to invalidity actions (absolute/relative grounds).

[23] From Art. 63 - bis to Art. 63 - terdieces of Decree of the Minister of Economic Development No 33 of 13 January 2010 and following amendments.
[24] Art. 63 - decies of Decree of the Minister of Economic Development No 33 of 13 January 2010 and following amendments.

HOFFMANN EITLE's Italian trademark attorneys in Milan are at your disposal for any further information or assistance on this matter.

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Opposition to French Patents – A First Assessment

Since April 2020, a new procedure introduced under French Patent Law allows the opposition of granted national patents[1] before the French National Institute of Intellectual Property (INPI). Compared to the better-known opposition procedure of the European Patent Office (EPO), some aspects of French opposition appear to make it more patentee-friendly, namely:

- Due to the procedural rules and the conduct of the opposition boards of INPI, patentees have more opportunities to file amendments than the opponents are given to file new documents, facts or evidence in support of the opposition;
- The opposition boards of INPI seem to systematically check whether the patent can be maintained unamended (even in the case where the patentee only defends amended claims), and whether any granted dependent claim would be allowable, if the related independent claims (granted or amended) are not.

Although it is too soon to confirm any statistically significant differences between the French and EPO opposition procedures, the outcome of French opposition procedures appears to be more favourable to patentees than those at the EPO (less than 20% full revocation versus more than 33%).

Summary of the French opposition procedure

This major change in French patent law entered into force on April 1, 2020. Similar to the EPO procedure, the opposition to a French patent must be filed within 9 months from the publication of the mention of grant of the French patent,[2] which requires, *inter alia*, submitting substantiated grounds of opposition and paying an opposition fee.[3]

A French patent can be opposed on the same grounds as a European patent, namely added subject-matter, lack of sufficiency/enablement, and patentability,[4] and can be filed by any person except the patentee itself.[5]

Once found admissible, a French opposition procedure includes four phases:[6]

1) the patentee's response to the opposition including observations and/or amendments;
2) a preliminary opinion issued by an opposition board of the INPI;
3) written proceedings with:
   - a first round where each party is given an opportunity to comment on the preliminary opinion (the patentee having another opportunity for amendments), and,
   - if any submission was made in response to the preliminary opinion, a second round where each party is given an opportunity to comment on the other party's submission (and the patentee has yet another opportunity for amendments);
4) oral proceedings, if requested by any of the parties or at the behest of the INPI.

So far, at least thirteen written decisions have been issued since May 23, 2022,[7] allowing some initial lessons.

[1] Only patents examined and granted by the INPI can be opposed before the INPI, not European patents validated in France, French utility models or French SPCs.
[2] See article R613-44 of the French IP Code (FIPC).
[3] See article R613-44-1 FIPC. The opposition fee currently amounts to €600.
[4] See article L613-23-1 FIPC.
[5] See article L613-23 FIPC.
[6] See article R613-44-6 FIPC.
[7] This article is based on a study of these thirteen decisions, and three other oppositions for which detailed minutes of the oral proceedings have been issued (but not the written decision yet).

An appeal against an opposition decision can be lodged before the Paris Court of Appeal.[8] Given its judicial nature, the appeal decision is in principle res judicata.[9] The question therefore arises as to whether the same opponent is entitled to challenge again the validity of the same patent during a subsequent legal action before the French Courts. Until jurisprudence provides some certainty in this respect, several opponents have taken the safe option of filing their oppositions through an intermediary (e.g. a strawman). This trend is clearly illustrated by the oppositions already decided, more than a third of which were filed by such intermediaries.

Differences with EPO procedure

Although very few decisions are available, the French opposition procedure appears to be generally more favourable to patentees than that of the EPO.

First, the rules of the procedure allow the patentee to file amendments during the written proceedings, after the preliminary opinion of the INPI,[10] whilst any new facts and evidence filed by the opponent during the same period is considered late-filed and thus only admitted at the discretion of the opposition board.[11] This asymmetry seems to contrast with EPO practice requiring the parties to be treated equally. And although opposition boards are instructed to be lenient in admitting new prior art submitted in reaction to amendments taken from the description,[12] they seem on the other hand to strictly refuse to admit new prior art submitted in reaction to amendments based on features of the claims as granted.[13]

Secondly, the conduct of the opposition boards appears to favour the patentees as well. Any amendment or new fact or evidence filed after the conclusion of the written proceedings is deemed late-filed. In several decisions however, the opposition boards appear to have admitted any amendment to the patent, even when filed as late as the day of the oral proceedings. This was made under the provisions that a decision may be based on late-filed facts or evidence, provided that the parties have been able to discuss them in adversarial proceedings,[14] and that the oral proceedings "are an adversarial phase by nature".[15] In a more recent decision however, the opposition board did not admit claim amendments as these were based on the description and filed on the day of the oral proceedings. This was considered to prevent the opposition board and the opponent from assessing the new claimed matter or having an adversarial discussion.[16]

Third, in the case that the patentee files amended claims as a main request, the opposition board still initially checks whether the opposition is prejudicial to the maintenance of the independent claims as granted.[17] Additionally, if none of the independent claims (granted or amended) are allowable, the opposition boards seem to systematically check whether at least one of the granted dependent claims is allowable.[18] In that case, a decision of partial revocation of the patent is issued.[19]

[8] See articles L411-4, R411-19 and D411-19-2 FIPC.
[9] This means that the same matter can in principle not be re-litigated by the same parties in any court.
[10] See article R613-44-6 FIPC.
[11] See decision OPP21-0012.
[12] See INPI Guidelines « Procédures Post-délivrance Brevet », June 2021 edition, p. 35.
[13] See decision OPP21-0010, where new prior art was deemed inadmissible, regardless of its relevance, even though it was filed before the oral proceedings and in direct reaction to a non-straightforward combination of granted claims.
[14] See article R613-44-7 FIPC.
[15] See decisions OPP21-0002, OPP20-0003, OPP20-0004, and OPP21-0005, all of which admitted amendments submitted on or shortly before the day of the oral proceedings.
[16] See decision OPP21-0007.
[17] See decisions OPP20-0003, OPP21-0002, OPP21-0003, OPP21-0004, OPP21-0010, and OPP21-0014.
[18] See decision OPP21-0007, and the minutes of the oral proceedings in opposition OPP21-0015 for which the written decision has not yet been issued.
[19] See article L613-23-6 FIPC.

Although the small number of decisions by the INPI does not lend to a true statistical analysis, we note that, at the INPI, less than 20% of the decisions led to a full revocation,[20] whereas this number is more than 33% at the EPO.

This difference is all the more remarkable given that, until recently, French national patents were refused only for manifest lack of novelty,[21] and thus enjoy a lower presumption of validity than patents granted by the EPO. It will therefore be interesting to see whether the results of French opposition procedure differ from that of the EPO in the longer term, perhaps as a result of the differences in procedural rules and practice mentioned above.

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[20] Of the 16 decisions identified (included those for which the written decision is not yet issued), only three led to a full revocation of the patent (namely OPP21-0007, OPP21-0012, and OPP21-0015).

[21] Novelty and inventive step have become grounds for refusal at the INPI for patent applications filed on or after May 22, 2020. All patents for which opposition decisions have been issued so far were filed before this date (and were therefore only examined for manifest lack of novelty).

Late-Filed Inventive Step Submissions – Lessons From T 1042/18

T 1042/18[1] sets a high bar for admitting inventive step objections late during EPO appeal proceedings. Even if, in the opponent's view, a claim lacks novelty in view of a piece of prior art, the opponent must come forward with specific inventive step objections, at least on an auxiliary basis, at the beginning of the appeal proceedings. Otherwise, the objections may be rejected as late filed. We examine T 1042/18 and its consequences in practice.

The case law before decision T 1042/18

The Enlarged Board of Appeal clarified in decisions G 10/91, G 1/95, and G 7/95 that each ground for opposition has to be substantiated separately.[2] The grounds for opposition not only include each of Article 100(a), (b) and (c) EPC, but each legal basis within Article 100(a) EPC also constitutes a separate ground for opposition. That is, the ground of unpatentable subject-matter based on Articles 52(1), (2), and (3) EPC, the lack of novelty based on Articles 52(1) and 54 EPC, and the lack of inventive step based on Articles 52(1) and 56 EPC are separate grounds for opposition.

The Boards of Appeal decision T 131/01,[3] confirmed by T 635/06 and T 597/07, ruled that the logical and substantive connection between novelty and inventive step has an influence on the requirement of substantiation of a ground of lack of inventive step based on a prior art document if lack of novelty is asserted based on the same prior art document. Namely, if a prior art document anticipates the subject-matter of a claim, it necessarily follows that this subject-matter cannot be inventive and formulating both attacks in parallel, based on the same piece of prior art, leads to contradictions within the attacks. In other words, an opponent can in principle, from a logical point of view, only formulate a substantiated inventive step attack by first assuming that the subject-matter at stake is new, which would thus contradict the novelty attack previously presented by the opponent.

In view of this, the Board held in T 131/01 that a substantiated novelty attack and the precautionary mention of an inventive step attack using the same document (should the novelty attack fail) were sufficient for the ground of inventive step to be considered substantiated and thus not to constitute a fresh ground for opposition.[4]

The case underlying the decision T 1042/18

In the first instance proceedings underlying T 1042/18, the opponent alleged, among other things, that the opposed patent lacked novelty in view of each of prior art documents D4 and D5. Inventive step starting from these documents was not discussed in the notice of opposition. The Opposition Division did not follow the opponent's reasoning and found claim 1 as granted to be new and inventive over the cited prior art, hence rejecting the opposition.

In their grounds of appeal, the appellant-opponent maintained their novelty attack using each of D4 and D5, but, again, did not elaborate on inventive step starting from either of them. Only during the oral proceedings before the Board of Appeal, the appellant argued that claim 1 as granted lacked inventive step starting from each of D4 and D5.

[1] T 1042/18 of 11 May 2022.

[2] The Enlarged Board also found that an Opposition Division may consider other grounds for opposition than those properly submitted and substantiated in application of Article 114(1) EPC if they are prima facie relevant, but that, in appeal proceedings, such fresh grounds for opposition may only be considered with approval by the patentee.

[3] T 131/01 of 18 July 2002.

[4] The Board also held that, as a consequence, in this scenario, as no fresh ground for opposition was introduced into the proceedings, approval by the patentee was not required for discussing inventive step.

The appellant also referred to the above-discussed case law and argued that, in view of the novelty attack using D4 and D5, the Board should admit the inventive step attacks based on these documents into the appeal proceedings.

In particular, the appellant argued that Article 13(2) of the Rules of Procedure of the Boards of Appeal (RPBA)[5] should not render the existing case law obsolete, that is, should not stand in the way of admitting the inventive step attacks based on T 131/01.

The Board's reasoning in T 1042/18

The Board did not follow the appellant's arguments and instead found that the existing case law, in particular T 131/01, relates to the admissibility of an inventive step attack in view of whether a fresh ground for opposition is present or not (first criterion), while Article 13(2) RPBA relates to the admissibility of late filed submissions during appeal proceedings (second criterion). The Board considered these two criteria to be independent and cumulative.[6]

The first criterion relates to whether a fresh ground for opposition is present or not, whereas the second relates to whether the appeal case has been amended at a late stage of the proceedings. In the Board´s view, these two criteria for deciding on the admissibility of the inventive step attack hence relate to entirely different spheres.[7]

In other words, it is possible that a lack of inventive step attack may be admissible as not constituting a fresh ground for opposition, but at the same time inadmissible in view of Article 13(2) RPBA and hence inadmissible as a whole since, in the Board's view, one reason in favor of admissibility does not outweigh another reason in favor of inadmissibility. Instead, a single reason for considering a submission inadmissible is sufficient to render the submission inadmissible.

The Board further held that these two aspects were clearly not the same as a fresh ground for opposition is usually an amendment of the appeal case while the opposite is not true.

The Board moreover elaborated why, in line with decision J 14/19, the objection of lack of inventive step of claim 1 as granted based on document D4 or D5 presented for the first time in the oral proceedings before the Board of Appeal indeed constitutes an amendment of the appeal case and thus Article 13(2) RPBA is indeed applicable.[8]

Finally, the Board held that the reference to T 131/01 does not constitute exceptional circumstances in the sense of Article 13(2) RPBA, in particular as the points discussed therein do not relate to the procedural aspects to be assessed in light of Article 13(2) RPBA but rather the question whether a fresh ground for opposition exists.[9]

Subsequent case law

Several boards have since confirmed the approach adopted by Board 3.2.02 in T 1042/18.[10]

In T 1816/17,[11] Board 3.2.02 in a different composition, having dealt with six inventive step attacks presented by the opponent, considered whether a seventh one starting from D1, which had been used for a novelty attack, should be admitted into the proceedings. The Board noted that the inventive step attack starting from D1 had not been substantiated prior to the notification of the summons to the oral proceedings before the Board and thus constituted an amendment to the party's appeal case under Art. 13(2) RPBA. As in T 1042/18, the opponent relied on T 131/01, T 635/06, and T 597/07, but the Board again held that these decisions did not take precedence over Art. 13(2) RPBA, and the Board did not admit the inventive step attack into the proceedings.

[5] For a discussion of Article 13(2) RPBA and related provisions, see for example: Johannes Osterrieth, Nicolas Douxchamps, Morten Garberg, "The EPO Rules of Procedure of the Boards of Appeal (RPBA) – An Update Two Years After the Entry Into Force of the RPBA 2020 (part I)", HOFFMANN EITLE Quarterly, December 2021, pp. 2-5.

[6] T 1042/18, reasons 4.5.

[7] Ibid., reasons 4.8.

[8] Ibid., reasons 4.9.

[9] Ibid., reasons 4.10.

[10] The three decisions discussed in this section are examples of cases in which the reasoning of T 1042/18 was applied. Other decisions applying the same principles exist, such as T 2866/18 of 4 October 2022, reasons 4, and T 1179/17 of 14 June 2022, reasons 4.6.2.

[11] T 1816/17 of 13 May 2022, reasons 12.

In the case underlying T 2161/18,[12] while the Opposition Division had found the claims to be new over a document D15, the opponent waited until their response to the summons to oral proceedings in appeal to raise for the first time an inventive step attack starting from D15, and the opponent again invoked T 131/01. Board 3.3.03 was not impressed and rejected the inventive step attack as late-filed on the basis of Art. 13(2) RPBA.

In T 151/19,[13] the opponent had duly raised a novelty attack using a document D2 in their statement of grounds of appeal, and then, almost one year after the proprietor's reply to the grounds of appeal, raised an inventive step attack starting from D2. Board 3.2.06 noted that the opponent had been aware of which features were considered absent in D2 already from the first instance proceedings, including from the Opposition Division's decision, so that "*the opponent would already have had reasons to raise its inventive step objections in a complete manner with the statement of grounds of appeal*".[14] The Board rejected the inventive step attack this time under Art. 13(1) RPBA, referring to T 1042/18.[15]

Consequences in practice

As a consequence of T 1042/18, in order to ensure that not only a lack of novelty attack but also a lack of inventive step attack is admitted into the appeal proceedings, reliance on the case law established with T 131/01 should be paired with appropriate consideration for Article 13(2) RPBA.

One way to achieve this is to substantiate with the grounds of appeal (or the reply thereto, respectively) the inventive step attack as far as possible, duly taking the reasoning in the first instance decision into account. That is, if an Opposition Division finds that a claim is both new and inventive over a piece of prior art, an opponent in appeal must duly address, in its statement of grounds of appeal (or in its reply to the patentee's statement of grounds of appeal), the Opposition Division's existing reasoning regarding inventive step —making assumptions on an auxiliary basis if necessary— even if the opponent also does not agree with the Opposition Division's finding that the claimed subject-matter is new over that same piece of prior art.

As T 1042/18 does not invalidate the general findings in T 131/01, it also remains advisable when preparing a notice of opposition to include, after presenting a novelty attack using a piece of prior art, a precautionary statement to the effect that, in case the patentee should contest the arguments relating to novelty, the claimed subject-matter in any event does not involve an inventive step starting from that same piece of prior art.

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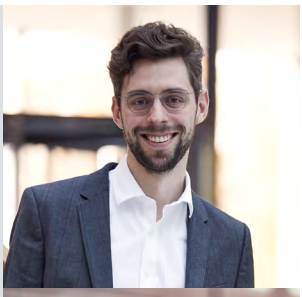

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[12] T 2161/18 of 24 May 2022, reasons 5.4.

[13] T 151/19 of 22 September 2022, reasons 3.7.

[14] Ibid., reasons 3.7.1, fourth paragraph.

[15] Interestingly, the Board went even further and noted, in reasons 3.7.6, that the statement "*Should for any reason the Main Request be considered novel over D2, then it is submitted that depending on the difference considered to be present, based on any of the above mentioned reasoning for that difference, it cannot be considered inventive*" did not constitute a substantiated inventive step attack. This appears to highlight the necessity, at the latest at the beginning of the appeal proceedings, to make assumptions, at least on an auxiliary basis, about the existence of distinguishing features when raising an inventive step attack based on a document that has been also used for a novelty attack.

Abolition of the EPO's "Ten-Day Rule": Simplification and Closing of Gaps

The European Patent Convention (EPC) currently stipulates that a communication is deemed delivered ten days after the date the EPO stamps on the document. This will no longer be the case as of November 1, 2023, bringing an end to the "ten-day rule".

On October 13, 2022, the Administrative Council of the European Patent Organisation amended the Implementing Regulations to the EPC.[1] As a result, the so-called "ten-day rule" will no longer apply to communications notified by the European Patent Office (EPO) on or after November 1, 2023. This means that, wherever a time limit is triggered by the notification of a communication,[2] its calculation will change.

Deemed delivery and time limit calculation

Under the current regime, a document received from the EPO is deemed to be delivered to the addressee *on the tenth day* following its handover to the postal service provider (for delivery by postal service - Rule 126(2) EPC) or its transmission (for electronic communications - Rule 127(2) EPC). In the era of electronic communication, this is usually the tenth day after the date the document bears. It is after this ten-day period that the computation of any period triggered by the notification starts.

This will change on November 1, 2023. According to amended Rules 126(2) and 127(2) EPC, a document from the EPO will be deemed to be delivered to the addressee *on the date it bears*, irrespective of whether the notification is effected by postal service or electronic communication. Therefore, the computation of any period triggered by the notification will directly start after the date of the document.

If there is any dispute concerning the delivery of a document, the EPO will retain the burden to establish that the document has been indeed delivered and when this delivery occurred. The safeguard provisions in case of a late delivery will thus be brought into conformity with Rule 80.6 PCT. That is, where a communication was received more than seven days after the date it bears, the applicable time limit will be extended by the number of days by which the communication was received later than seven days after the date it bears.

The abolition of the ten-day rule will simplify the time limit calculations. On the other hand, the ten-day rule has often been used by EP representatives as a "buffer period" in the communication with clients, during which final changes to a response could be agreed upon, and the rule is known to some outside of Europe as well. Therefore, in order to avoid any miscalculation of time limits, it is important to be aware of the forthcoming abolition of the ten-day rule.

Effects on further EPO procedures

Interestingly, the abolition of the ten-day rule may have an impact on the EPO practice when a party is summoned to oral proceedings. At present, a summons must be issued by the EPO at least *two months and ten days* before the date of oral proceedings (unless the parties consent to a shorter period).

[1] Source:
- Decision of the Administrative Council of 13 October 2022 amending Rules 46, 49, 50, 57, 65, 82, 126, 127 and 131 of the Implementing Regulations to the European Patent Convention *(CA/D 10/22)*
- Notice from the European Patent Office dated 25 November 2022 concerning legal changes to support digital transformation in the patent grant procedure

[2] Including "[d]ecisions, summonses, notices and communications" (Art. 119 EPC).

Indeed, the summons is deemed delivered on the tenth day after the date of the summons, and at least two months' notice of the summons must be given according to Rule 115(1) EPC. Under the amended regulations, the summons will be deemed delivered on the date of the summons. As a result, the EPO will be able to issue a summons to oral proceedings *just two months* before the date of oral proceedings.

Another possible impact is in the appeal proceedings, where the admissibility of an amendment to a party's appeal case is assessed in line with the three-level convergent approach.[3] Under Article 13(2) of Rules of Procedure of the Boards of Appeal (RPBA), after *notification* of a summons to oral proceedings, an amendment to a party's appeal case shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned (third level of the convergent approach). The notification of the summons occurs *on the tenth day* after the date of the summons. Before this date, the Board has the discretion to admit an amendment to a party's appeal case in line with Article 13(1) RPBA (second level of the convergent approach). This means that, under current regulations, a party still has a "gap" of *ten days* after the date of the summons until the strict provisions of Article 13(2) RPBA apply.[4] The amendments to Rules 126(2) and 127(2) EPC will close this gap. Hence, the strict third level of the convergent approach will start to apply on the date of the summons.

Conclusion

The upcoming abolition of the ten-day rule is a very important change to the EPO practice which will force EP representatives and their clients worldwide to monitor approaching deadlines even more carefully than in the past.

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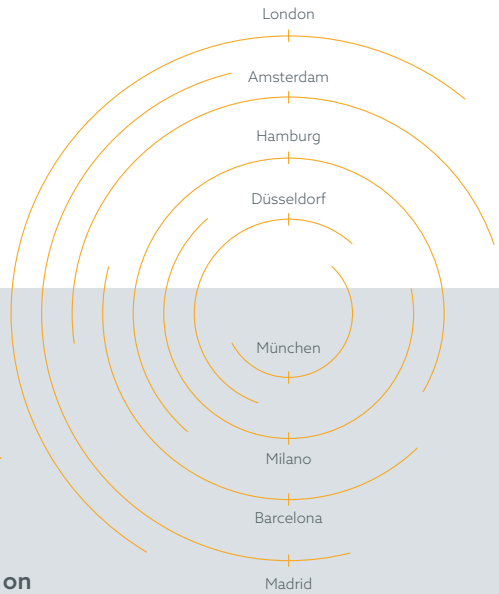
[3] See Johannes Osterrieth, Nicolas Douxchamps, Morten Garberg, "The EPO Rules of Procedure of the Boards of Appeal (RPBA) – An Update Two Years After the Entry Into Force of the RPBA 2020 (part I)", HOFFMANN EITLE Quarterly, December 2021, pp. 2-5.

[4] See T 311/20 of 18.10.2021, Reasons 3.3.1.



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