D YOUNG & CO
INTELLECTUAL
PROPERTY

European biotech patent case law

14 July 2026

Speakers

Simon O’Brien
Partner, Patent Attorney
swo@dyoung.com

Tom Pagdin
Partner, Patent Attorney
twp@dyoung.com

Summary

- **T 265/23** – credible therapeutic effect
- **An update on G 2/21** – post-published evidence to support an improved technical effect

T 265/23 – credible therapeutic effect

Combination of two antivirals for treating Hepatitis C
AbbVie Inc

Background

- For medical use claims, the attainment of the therapeutic effect is a functional feature of the claim.
- The application must disclose the **suitability** of the composition for the claimed therapeutic use, **unless this is already known** to the skilled person at the priority date (T 1868/16, T 609/02, T 433/05, T 801/06).
- Mere verbal statements are not enough. The patent application must provide some information, e.g. experimental tests showing that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease.
- Clinical data are not always required. *In vitro* examples may be sufficient.
- Post-published evidence may be taken into account, but only to back up the findings in the application (T 609/02).

“Suitable” test for medical use claims

- T 801/06 (citing T 609/02), r.28:
  - a claimed therapeutic effect may be proven by **any kind of data** as long as they clearly and unambiguously reflect the therapeutic effect
- T 609/02 (citing T 158/96), r.9:
  - the application must disclose the **suitability** of the product to be manufactured for the claimed therapeutic application
  - the patent system takes account of the intrinsic difficulties for a compound to be officially certified as a drug by **not requiring an absolute proof** that the compound is approved as a drug before it may be claimed as such
  - an *in vitro* effect may be sufficient if the observed effect directly and unambiguously reflects such a therapeutic application or if there is a "*clear and accepted established relationship*" between the shown physiological activities and the disease (T 158/96)
  - once this evidence is available, then post-published expert evidence may be taken into account, but only to back-up the findings in the patent application and not to establish sufficiency of disclosure on their own.

T 265/23

- AbbVie's patent EP3213750, filed 14 March 2014.
- A **combination** of glecaprevir (a protease inhibitor) and pibrentasvir (an NS5A inhibitor) **for use in a method for treatment** of HCV infection
  - wherein neither interferon nor ribavirin are administered during treatment
  - treatment lasts for 16 weeks

T 265/23 - prior art

- **D6** and **D7** each disclose single agents (glecaprevir and pibrentasvir, respectively) for treating HCV infection.
- **D6** and **D7** each contained *in vitro* data relating to the single agents.
- Each taught that the compound could be administered alone, or in combination with other anti-HCV agents, such as NS5A inhibitors or HCV protease inhibitors.
- Neither **D6** nor **D7** disclosed the other **specific** agent.
- Thus, the combination of glecaprevir and pibrentasvir is not disclosed in the prior art, which only comprises *in vitro* data for the single agents.

T 265/23 – information in the patent

- Patent describes glecaprevir and pibrentasvir as “potent” protease or NS5A inhibitors and cross-references D6 and D7.
- Example 1 – ***in silico*** modelling of combination therapy using modelling methods **cross-referenced** in **D3.**
- Example 2 – ***in vitro*** data showing effect of glecaprevir on HCV inhibition and ***in silico*** data showing synergistic effect for the combination.
- The patent did **not** disclose any clinical data.
- The patent did **not** disclose any *in vitro* data for the combination.

T 265/23 – opponent's arguments

- The patent in suit did not disclose the suitability of the claimed combination for the therapeutic application because:
- No clinical data were reported.
- Examples 1 and 2 did not demonstrate any effect of the combination of glecaprevir and pibrentasvir on a metabolic mechanism directly involved in HCV infection.
- It was not permissible for the patentee to rely on the disclosure of clinical modelling in **D3** as this document **was not CGK.**

T 265/23 – board's opinion

- Glecaprevir and pibrentasvir had been previously described and were known to have anti-HCV activity based on two different mechanisms.
  - Here, the BoA referred to paragraphs in application citing D6 and D7, but it is not clear whether the cross-referencing of D6 and D7 in the patent was decisive.
- On this basis, in combination with the further data provided in the application, and in the absence of evidence to the contrary, it would have been credible that the combination of these agents provides anti-HCV activity.

T 265/23 – board's opinion

- Example 1 relates to mathematical clinical modelling and shows sustained virological response for the claimed therapy (combination, 16 weeks, without interferon/ribavirin).
- The patentee explained that modelling is an **established approach** for predicting the efficacy of anti-HCV drugs.
- Board held that **D3** (describing the model) does not have to be part of the CGK **since it is cross-referenced in the application.**
- Thus, the application contains sufficient evidence, going beyond mere verbal statements, of a mechanism and technical concept that supports the suitability of the combination for the therapeutic application.
- Post-published evidence may be taken into account for confirmation. D11 (EMA approval) confirms the suitability of the combination for HCV treatment.

T 265/23 – inventive step over same prior art?

- D6 (glecaprevir) was considered the closest prior art.
- A combination treatment with glecaprevir and a further anti-HCV agent is envisaged but not put into clinical practice in D6.
- D6 teaches treatment with **or** without interferon and ribavirin (i.e. a selection is required).
- Claim 1 therefore differs from D6 in that:
  a) the treatment of an HCV patient with a combination of glecaprevir and a further anti-HCV agent is **put into clinical practice**
  b) pibrentasvir is chosen as the further anti-HCV agent
  c) the treatment duration is 16 weeks
  d) the concomitant administration of interferon and ribavirin is excluded

T 265/23 – inventive step

- Opponent argued that the patent did not disclose putting the claimed therapeutic application into clinical practice either.
- Board held that since attaining the claimed therapeutic effect in clinical practice is present as a functional technical feature in current claim 1, this feature has to be taken into consideration as a distinguishing technical feature of claim 1 in comparison with the disclosure in D6.

T 265/23 – obviousness

- It would have been a consideration to test and implement combination treatments without interferon and ribavirin in view of D6.
- The more specific question that had to be answered was whether, in view of the prior art, it would have been obvious for the skilled person to **choose pibrentasvir as the combination partner** to solve the objective technical problem. This includes whether there would have been a **reasonable expectation of success** for a viable combination treatment with glecaprevir and pibrentasvir that does not require co-administration of interferon and ribavirin.
- **D6** teaches the combination partner may be an NS5A inhibitor, among other possibilities.
- Pibrentasvir is one of over 150 anti-HCV agents in **D7** but is not identified as an NS5A inhibitor.

T 265/23 – obviousness

- "As to the obviousness of combining glecaprevir with pibrentasvir, the content of D6 and D7 (both published less than a year before the priority date) suggests that both compounds were still at an **early stage of development**… it would thus appear that the individual **therapeutic efficacy and safety of these compounds had yet to be assessed**. **Only *in vitro* data for the single compounds are provided in D6 and D7**, and there is no teaching in either document about therapy duration or other potential details of a combination therapy to be administered to HCV patients."
- There was no direct route that would have led to the development of the claimed combination with a reasonable expectation of success.

T 265/23 – take home considerations

- It may be possible to rely on *in vitro* data for individual agents in the prior art to render credible a therapeutic effect for a combination.
- In certain circumstances, in silico data can be used in absence of wet data.
- Cross-referencing documents is important if you intend to rely on them for sufficiency, especially if the document does not form part of the CGK.
- The second medical use claim is interpreted as treatment which is put into clinical practice.
- The absence of clinical data in the prior art for the individual agents may contribute to a finding of inventive step (due to lack of reasonable expectation of success) for the combination.

An update on G 2/21

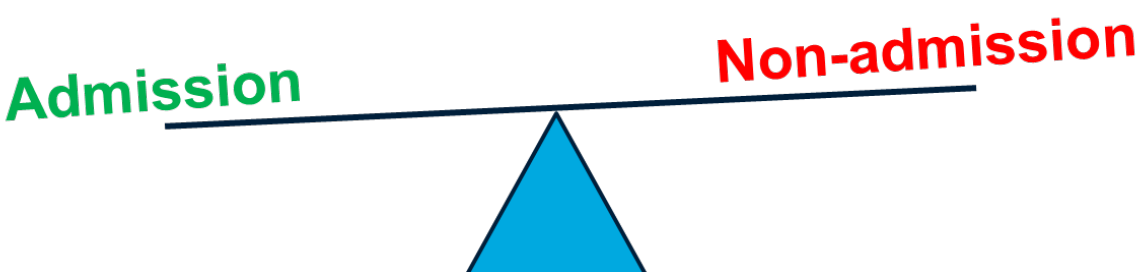
Post-published evidence to support inventive step

G 2/21: background

"*A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed,* ***would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention***."

Factors for applying G 2/21 test

- Is the effect “encompassed by” the technical teaching and “embodied by” the same originally disclosed invention?
  1. Is a **relationship** between the claimed matter and effect known?
  2. Are there any **reasons to doubt** the effect?
  3. Is the selected embodiment **preferred** in any way?



Interpretation of G2/21: post-published evidence and “improved” technical effects

Previous case law

- Post-published evidence could be relied on:
  - **T 1989/19** – reliance on post-published evidence to substantiate an improvement was considered permissible as the technical effect itself was already derivable from the application as filed.
  - **T 0840/22** – confirmed that post-published data may substantiate an improvement of an encompassed technical effect even if the superiority of one originally disclosed embodiment was recognised only later.
  - **T 2716/19** - improvement was recognised as a fundamental objective of the disclosed method.
- Post-published evidence could not be relied on:
  - **T 1994/22** – improved property of one polymorph over another was disclosed in the post-published document, but the polymorphs were disclosed on equal terms in the application as filed.
  - **T 0314/20** – application as filed disclosed several combinations at an equal level of preference that all achieved the same technical effect, the post-published document asserted a superior effect for one specific combination.
  - **T 0887/21** – post-published evidence concerned an asserted technical effect that could not be derived from the application as originally filed.

Previous case law

- Post-published evidence could be relied on:
  - **T 1989/19** – reliance on post-published evidence to substantiate an improvement was considered permissible as the technical effect itself was already derivable from the application as filed.
  - **T 0840/22** – confirmed that post-published data may substantiate an improvement of an encompassed technical effect even if the superiority of one originally disclosed embodiment was recognised only later.
  - **T 2716/19** - improvement was recognised as a fundamental objective of the disclosed method.
- Post-published evidence could not be relied on:
  - **T 1994/22** – improved property of one polymorph over another was disclosed in the post-published document, but the polymorphs were disclosed on equal terms in the application as filed.
  - **T 0314/20** – application as filed disclosed several combinations at an equal level of preference that all achieved the same technical effect, the post-published document asserted a superior effect for one specific combination.
  - **T 0887/21** – post-published evidence concerned an asserted technical effect that could not be derived from the application as originally filed.

T 0840/22: post-published evidence could be relied on

- Claim related to a multilayer coated metal substrate
- **Two equivalent embodiments** disclosed:
  - (1) the corrosion-inhibiting components being the **same**;
  - (2) the corrosion-inhibiting components **differing** from each other
- The board admitted post-filed data showing that embodiment (2) has **improved corrosion resistance** compared to embodiment (1)

T 0840/22: post-published evidence could be relied on

"*The fact to which the appellant took offence,* ***namely that one of several embodiments disclosed in the application as filed turns out to be better…does not change this conclusion…this scenario is precisely what regularly occurs in patents/patent applications in the field of chemistry,*** *where claimed subject-matter must be limited at the expense of subject-matter disclosed in the application as filed as part of the invention, because the effect relied on for inventive step over the closest prior art is not achieved across the entire breadth of the claimed subject-matter*"

Previous case law

- Post-published evidence could be relied on:
  - **T 1989/19** – reliance on post-published evidence to substantiate an improvement was considered permissible as the technical effect itself was already derivable from the application as filed.
  - **T 0840/22** – confirmed that post-published data may substantiate an improvement of an encompassed technical effect even if the superiority of one originally disclosed embodiment was recognised only later.
  - **T 2716/19** - improvement was recognised as a fundamental objective of the disclosed method.
- Post-published evidence could not be relied on:
  - **T 1994/22** – improved property of one polymorph over another was disclosed in the post-published document, but the polymorphs were disclosed on equal terms in the application as filed.
  - **T 0314/20** – application as filed disclosed several combinations at an equal level of preference that all achieved the same technical effect, the post-published document asserted a superior effect for one specific combination.
  - **T 0887/21** – post-published evidence concerned an asserted technical effect that could not be derived from the application as originally filed.

T 0314/20: post-published evidence could not be relied on

- Claim related to the combination of empagliflozin and linagliptin
- Post-filed data show that the claimed combination increased the plasma level of active GLP-1 in patients with diabetic diseases in a **stronger and more prolonged manner** than the **other two combinations** described in the application
- The board did not admit the post-filed data

T 0314/20: post-published evidence could not be relied on

- The application disclosed that the other combinations had the **same level of preference** and achieve the **same increase** in plasma levels of active GLP-1 in patients as the claimed combination.
- "*the skilled person, would **not** derive the **increase in plasma levels of active GLP-1 relied on** by the respondent as being encompassed by the technical teaching of the claimed invention and embodied by the same originally disclosed invention*"

Latest case law:

How are the Boards of Appeal assessing “improved” technical effects?

Has the post-G2/21 case law landscape changed?

Latest case law: T 0592/24

T 0592/24 - background

- Combination of **ribociclib and letrozole** for use in treating hormone sensitive and/or hormone-receptor positive cancer
- The combination of **palbociclib and letrozole** was considered as the closest prior art
  - Also claimed in the original application as filed (e.g. claim 7 as filed)
- Ribociclib + letrozole = greater degree of synergy (compared to palbociclib + letrozole)
  - An improved technical effect, shown by *in vitro* + *in vivo* data
- Set up of clinical studies was described in the patent, **no** clinical data was disclosed
- Synergy & improved overall survival were both argued as improved technical effects supporting inventive step
- Post-published documents disclosed clinical trial data showing an improved clinical effect in the form of significantly **greater overall survival** of patients with HR+/HER2- advanced breast cancer when treated with ribociclib + letrozole, compared to palbociclib + letrozole

T 0592/24 – decision

- *In vitro* experiments in the patent demonstrate an **increased level of synergy** for the claimed combination compared with the prior art combination.
- When performing the invention, the skilled person would **inherently** take into account any improvement in overall survival of patients resulting from treatment with the claimed combination.
- Board summarised previous decisions T 1994/22, T 314/20, T 840/22 and T 1989/19.

T 0592/24 – decision

"*According to the cited jurisprudence, post-published evidence may thus be relied upon in support of an improved effect over the prior art* ***where the underlying technical effect is derivable from the application as filed and the improvement is consistent with the original technical teaching***."

T 0592/24 – decision

"…*reliance on post-published evidence to demonstrate an improved technical effect of the claimed subject-matter over a further embodiment originally claimed does not normally change the nature of the invention,* ***as long as the technical effect is derivable from the application as filed and the improvement is not in contradiction with the original disclosure***."

T 0592/24 – decision

- The post-published documents support the conclusion that treatment with the claimed combination is associated with improved overall survival, compared to treatment with the prior art combination.
- The post-published documents **could be taken into account** to demonstrate inventive step.

T 0592/24 – key findings

- Post-published data (e.g. clinical results) may be relied upon to support of an improved effect over the prior art.
- But the underlying technical effect must be derivable from the application as filed and **the improvement must be consistent** with the original technical teaching.
- Clinical data is not necessarily required at filing to support a technical effect and can be filed as post-published data, if the application as filed supports the same technical effect.

Latest case law: T 0655/24

T 0655/24 - background

- Fc region mutant with specific mutations lacking binding to Fcγ receptors whilst retaining a plasma clearance rate similar to wild-type.
- Data supporting the improvement in the application.
- Additional data provided in post-published documents as evidence that the effect of further reduced effector function (i.e. an improved technical effect) was achieved by the claimed Fc region mutant.
- Patentee argued that if a technical effect was disclosed in the application as filed, an improvement of that technical effect is also implicitly derivable → post-published documents can therefore be relied upon.
  - The patentee's arguments appear to be in line with T 0592/24 .

T 0655/24 – decision

- The board disagreed with the patentee's reasoning regarding post-published evidence:

  "…*the board does not consider that an improvement of an effect, here further reduced effector functions mediated by the Fc region, is encompassed by the technical teaching and embodied by the same originally disclosed invention* ***merely because the effect itself (but not the improvement), was shown to be achieved in the application as filed***"

T 0655/24 – decision

- Board acknowledged that a different approach in T 1989/19, T 2716/19 and T 840/22:

> "*However, this board is of the view that* ***an improved effect that has not been credibly achieved at the filing (or priority) date cannot be considered as "encompassed by the technical teaching and embodied by the same originally disclosed invention*****.**
>
> *In other words, if acknowledging inventive step requires taking an improved effect into account, the invention must be considered to have been made at the filing (or priority) date.* ***Thus, this board is of the view that assessment of inventive step can only take effects into account which were achieved at the effective date****."*

T 0655/24 – decision

- Figure 3A of the patent itself provided evidence of a direct comparison between the claimed Fc region mutant and those of the prior art
- The Board found that the technical effect of reduced effector function was credible **and was improved** compared to the Fc region mutants of the prior art
- Inventive step acknowledged without the post-published evidence

Summary

- T 0592/24 reasoning appears broadly consistent with a line of previous decisions.
- T 0655/24 assessment seems to follow a stricter approach to improved technical effects and post-published evidence.
- Continue to monitor how G2/21 is applied in the context of improved technical effects.

Practice points

- Case law continues to develop post-G 2/21.
- Improvements over the prior art should be demonstrated in the application as filed as much as possible.
- If data is not available at the time of filing and post-published evidence will need to be relied upon, the underlying technical effect must – at least – be derivable from the application as filed and **the improvement must be consistent** with the original technical teaching.

Next webinar
Tuesday 10 November 2026

Register at: dycip.com/webinar-biotech-nov2026

Questions

Simon O’Brien
Partner, Patent Attorney
swo@dyoung.com

Tom Pagdin
Partner, Patent Attorney
twp@dyoung.com