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Opinion

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The Assessment of Patent Validity by the Unified Patent Court

A little more than six months after the Unified Patent Court commenced its work, the judgment of the Court of Appeal in *10x Genomics v. NanoString* is the first final decision of the new court to deal in detail with the interpretation of an asserted patent claim and, based on this, with the assessment of the patentability of the subject-matter of a European patent. On the basis of this patent, a preliminary injunction was requested and issued by the Munich Local Division of the Court of First Instance. This fact alone shows that the significance of the decision can hardly be overestimated. A closer analysis of the decision confirms that it provides a wealth of insights into the way in which the UPC will deal with the questions of novelty and inventive step, which are at the centre of the examination of the validity of a patent in proceedings for interim measures, but also in proceedings on the merits. This article attempts to summarise the most important findings on substantive patent law and its application that can be derived from the decision of the UPC Court of Appeal.

I. Introduction

The second-instance and therefore final judgment[1] of the Court of Appeal of the Unified Patent Court (UPCoA) of 26 February 2024 in *10x Genomics v. NanoString*[2] concludes proceedings in which the first-instance judgment[3] had already caused a considerable stir. On the one hand, this was due to the attention that the first decisions of the new court were certain to attract in Germany and Europe, and beyond. On the other hand, it was also due to the way in which the Munich Local Division (LD) judged a large number of difficult and complex patent law issues in proceedings for provisional measures in favour of the applicants – and thus in a 'patentee-friendly' manner.

I will briefly summarise this first instance decision because it is important for understanding and correctly classifying the Court of Appeal decision, and I will focus on the statements that are important for assessing the patentability of the subject-matter of the patent in suit.[4]

1. Parties and subject-matter of the dispute

The applicants (10x Genomics, Inc. and President and Fellows of Harvard College, hereinafter: 10x Genomics) sought a preliminary injunction against the defendants (NanoString Technologies, Inc., NanoString Technologies Germany GmbH and NanoString Technologies Netherlands B.V., hereinafter: NanoString) for direct and indirect infringement of European patent 4 108 782, requesting that NanoString be prohibited from using or offering for use in the UPCA member states a method for detecting a plurality of analytes in a cell or tissue sample, from offering suitable devices or decoder probes for this purpose without reference to the patent in suit or without imposing a contractual penalty in the event of use for the detection of RNA, and from offering or supplying detection reagents for the method.

The patent in suit, which was granted with unitary effect for the UPCA member states, is based on a divisional application relating to a divisional application which goes back to an international application published as WO 2013/096851 dated 21 December 2012 (parent application), which claims a (US) priority dated 22 December 2011. The grant of the patent was published

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1 The decision is referred to in the judgment as an 'Order of the Court of Appeal'. However, I do not consider myself bound by the sometimes somewhat unwieldy and inappropriate terminology of the Agreement on a Unified Patent Court (UPCA) and the Rules of Procedure – especially in the German version – and see myself confirmed in this by the Court of Appeal, which refers to the provisional measure of the CFI as '*einstweilige Verfügung*' (preliminary injunction) in the German language of the proceedings and to the patent on which it is ruling as '*Verfügungspatent*' (untranslatable; in the Court's official English translation: patent in suit).

2 UPC_CoA_335/2023, [2024] GRUR 527 – *10x Genomics v NanoString*. Regrettably, the decisions of the UPC have so far not been provided with paragraph numbers, as the CJEU, the Federal Court of Justice (Bundesgerichtshof, BGH) and other courts have done for years. I therefore use the paragraph numbers from the publication of the decision as [2024] GRUR-RS 2829.

3 LD Munich, 'Decision and Orders' of 19 September 2023 (UPC_CFI_2/2023). The judgment is published in [2023] GRUR 1513, but only excerpts of the passages in which the LD deals with the interpretation of the patent claim and the attacks on novelty and inventive step, which are particularly important in light of the appeal judgment, are reproduced. The decision is available in full (and with matching paragraph numbers) as [2023] GRUR-RS 25256.

4 For further legal issues discussed by the LD, see Matthias Leistner, 'Einstweilige Unterlassungsverfügung des EPG wegen Patentverletzung. Die Lokalkammer München bohrt dicke Bretter' [2023] GRUR 1578.

on 7 June 2023. NanoString has filed an opposition with the European Patent Office.

Firstly, the Local Division explains why it affirms its jurisdiction, why it considers the application to be admissible and why it considers both applicants to be entitled to file the application.[5] In the following section A IV, which is of primary interest to us, it then explains why it is – according to the heading – 'convinced of the validity of the patent in suit'.

2. Subject-matter and interpretation of the patent claim by the LD

To this end, the subject-matter of the patent in suit is first explained[6] and – in accordance with German tradition – broken down into features[7] (the numbering of the breakdown of features is shown below in square brackets[8]). For a better understanding of the decision, I will summarise this breakdown:

Claim 1 relates to a method for detecting a plurality of analytes in a cell or tissue sample, wherein the sample is mounted on a solid support [1], brought into contact with a composition comprising a plurality of detection reagents [2], and then incubated for a sufficient amount of time to allow the detection reagents to bind to the analytes [3].

The detection reagents in turn consist of a plurality of subpopulations [2.1], each of which targets a different analyte [3.1], and each comprise a probe reagent [3.2.1] targeting a specific analyte and at least one predetermined subsequence [3.2.2 and 3.2.3] conjugated thereto.

To detect the subsequences in a temporally sequential manner [4], (i) a set of decoder probes is hybridised with a subsequence [4.1]; this set in turn comprises a plurality of subpopulations [4.1.1], each of which carries a detectable marker producing a signal signature [4.1.2 and 4.1.3]. Then (ii) the signal signature is detected [4.2], (iii) removed [4.3] and (iv) steps (i) and (iii) are repeated using a different set of decoder probes to detect other subsequences [4.4]. The *temporal order of the signal signatures* can be used in this way – and this is the point of the invention – to identify a subpopulation of the detection reagents and thus to detect the analytes in the sample [5]. This use of different temporal sequences of signal signatures is intended to solve the problem addressed at the beginning of the description: only a small number of different and sufficiently clearly distinguishable colours (fluorophores or chromophores) are available for labelling.

After these statements, the LD turns to the interpretation of patent claim 1, or, more correctly, individual features thereof,[9] introducing this section of the Reasons with the sentence:

> 'The meaning of individual terms and features of the patent claim is disputed between the parties so that they require interpretation.'

The parties had disputed – with regard to prior art document D6[10] considered by NanoString to be prejudicial to novelty – among other things whether a 'cell or tissue sample' within the meaning of the patent claim could also consist only of the analyte to be identified in this sample. The LD believes that it is 'clear to a person skilled in the art' that the sample according to the claim is one that is still recognisable as a cell or tissue. According to the wording of patent claim 1, it is therefore impossible to qualify a part of the genomic DNA isolated and amplified from a cell as a cell or tissue sample. This is followed by comments on the concept of a subpopulation (feature 2.1) and on the question of whether feature 4.4. implicitly also presupposes the repetition of the second (detection) step (feature 4.2), which I will pass over here.[11]

3. The assessment of patent validity by the CFI

The next section of the grounds[12] states that 'for a sufficiently certain conviction of the validity of the patent in dispute, a preponderance of probability is necessary but also sufficient'. The burden of presentation and proof for the alleged lack of validity lies with the defendant.[13] The following two sections deal with the definition of a person skilled in the art and the negation of added matter.[14]

The LD then argues that, in its firm conviction, a revocation of the patent in suit is not to be expected.[15] The object of the detection in D6 is not cell or tissue samples but amplified single molecules (ASMs). Moreover, in D6 the bond between analyte and reagent is dissolved after each detection. The LD assumes that the patent in suit, in contrast to this, presupposes the continued existence of the bond between analyte and detection reagent.

It was also not to be expected that the subject-matter of patent claim 1 would be revoked for lack of inventive step.[16]

The (closest) prior art to be used to establish lack of inventive step is generally a prior art document which discloses an object developed for the same purpose or with the same aim as the claimed invention and having the main technical features in common with it, i.e. requiring the fewest structural changes.

5 A I to III of the Reasons ([2023] GRUR 1513 paras 74-111).

6 A IV 1 ([2023] GRUR 1513 paras 115-29).

7 A IV 2 ([2023] GRUR 1513 para. 131).

8 However, for the sake of simplicity, I will use the feature structure of the Court of Appeal and not the slightly different structure of the Court of First Instance.

9 A IV 3 ([2023] GRUR 1513 paras 132-46).

10 Jenny Göransson and others, 'A single molecule array for digital targeted molecular analyses' (2009) 37(1) Nucleic Acids Research e7. Where citation D6, referred to only as 'Göransson and others' in the judgment at first instance, was published is not mentioned and only emerges from the appeal judgment.

11 These statements *do not include* the sentence quoted in the appeal judgment (UPCoA, [2024] GRUR-RS 2729 para 21) at this point in the reproduction of the first instance Reasons that claim 1 presupposes the continued existence of the bond between the analyte and the detection reagent (feature 3) produced by incubating the cell or tissue sample with the detection reagents during the repetition of the detection steps. It is taken from the comments of the LD on the novelty of the subject-matter of the patent in suit, ([2023] GRUR-RS 25256 para 174, in this respect [2023] GRUR 1513 not reproduced).

12 A IV 4 ([2023] GRUR 1513 paras 147-51).

13 'A IV 3', correct: A IV 5 ([2023] GRUR 1513 paras 152-55).

14 'A IV 4 and 5', correct: A IV 6 and 7 ([2023] GRUR 1513 paras 156-65).

15 'A IV 6', correct: A IV 8 ([2023] GRUR-RS 25256 paras 166-76, insofar [2023] GRUR 1513 only partially reprinted).

16 'A IV 7', correct: A IV 9 ([2023] GRUR-RS 25256 paras 177-94, insofar [2023] GRUR 1513 only partially reprinted).

The court could not recognise that, as claimed by NanoString, the invention was suggested by document D8.[17] The solution principles were fundamentally different.[18]

Insofar as NanoString wanted to use D6 as prior art to prove the lack of inventive step of the patent in suit, the court – for reasons to be discussed in more detail below – did not follow this. Moreover, the skilled person would not have arrived at the invention by such a transfer since the claim requires that the detection reagents remain bound to the analytes, and D6, in which the bond between analytes and reagents is dissolved ('*after each imaging*'), gives no reason to adapt this measure.

4. Further content of the LD judgment

Finally, the LD states that the invention is disclosed in a way that it can be carried out by a skilled person.[19] It explains why it is 'convinced with sufficient certainty, i.e. with at least a high degree of probability' that NanoString infringes the patent in suit both directly and indirectly.[20] The request is in accordance with the Rules of Procedure,[21] and the ordering of provisional measures – without the provision of security[22] – is necessary and also justified after a balancing of interests.[23] The LD takes the view that the enforcement of a European patent without unitary effect, which must be carried out separately in all member states, is therefore not an equivalent means of enforcing rights in the event of infringement compared to the enforcement of a Unitary Patent before the UPC. That is why the argument that 10x Genomics delayed the enforcement of its rights before the national courts is irrelevant.

Many of these questions were not relevant for the Court of Appeal and, with one exception, it does not address them. This applies in particular to the question of whether the need to grant interim relief can be affirmed, as the LD believes, irrespective of the possibilities that the patent holder used – or did not use – before 1 June 2023 to obtain legal protection against the infringer under national patents and, in particular, under European patents without unitary effect. Even otherwise well-meaning reviewers of the first-instance decision have expressed doubts about this.[24]

II. The judgment of the Court of Appeal

The Court of Appeal briefly ruled that the appeal's objections to the jurisdiction of the LD, to the admissibility of the request for interim measures and to Harvard's entitlement to apply for interim measures were unfounded,[25] and then turned to the subject-matter of the patent in suit without further comment (Section 4 of the Reasons). This in itself is a statement whose significance becomes clear in section 4(d) of the Reasons which is devoted to the interpretation of claim 1 of the patent in suit.

1. The importance of the interpretation of the patent in suit

This section is prefaced by the sentence that claim 1 requires interpretation 'with regard to some of its features'.[26] This sentence appears inconspicuous, but it is precisely formulated and is of central importance. Its wording alone makes it clear that it is not a matter of interpreting 'individual terms and features' because these are 'disputed between the parties', as the LD had formulated.

Rather, it is a matter of grasping the content and meaning of the patent claim as a whole.[27] For this patent claim determines the content and scope of the exclusive right which has been assigned to the patentee for exclusive use with the grant of the patent and can therefore be enforced against third parties. At the same time, it is this subject-matter of the exclusive right defined by the patent claim which must be measured against the standard of prior art when examining novelty and inventive step, and against the standard of the original disclosure when examining added matter.[28]

The appeal judgment says this somewhat differently, but expressly states it at the end of the short subsection 4(d)(aa) of the Reasons (which is just over half a page long and after which the court turns to the interpretation of claim 1 of the patent in suit) when it remarks there that the principles outlined for the interpretation of a patent claim – more details below – apply equally to the

17 Dzifa Y Duose and others, 'Multiplexed and Reiterative Fluorescence Labelling via DNA Circuitry' (2010) 21 Bioconjugate Chem 2327-331.

18 As this would go too far, I will refrain from reproducing the (technically implausible and possibly based on a misunderstanding of D8) statements of the LD in this regard ([2023] GRUR-RS 25256 paras 181-84). The appeal judgment does not mention them.

19 'A IV 8', correct: A IV 10 ([2023] GRUR 1513 paras 195-203).

20 A V ([2023] GRUR 1513 paras 204-46).

21 A VI ([2023] GRUR 1513 paras 247-52).

22 Critical, Leistner (n 4) 1578 (1582). The Court of Appeal does not mention this when reproducing the grounds of the first instance decision, but – although not mandatory according to the grounds of its decision – reproduces NanoString's appeal (alternative) argument that it should at least be enabled to continue the challenged acts against the provision of security, and, in the extreme alternative, the effectiveness of the preliminary injunction should be made dependent on the provision of appropriate security by 10x Genomics, as well as 10x Genomics' response to this (*10x Genomics v NanoString* (n 2) paras 42 and 53).

23 A VII and VIII ([2023] GRUR 1513 paras 253-312).

24 Leistner (n 4) 1578 (1582 f). The Court of Appeal, which reproduces in one paragraph the LD's reasoning for the necessity of ordering interim measures, does not mention this aspect.

25 *10x Genomics v NanoString* (n 2) paras 57-64.

26 *10x Genomics v NanoString* (n 2) para 72.

27 cf only BGHZ 159, 221 (226) – *Drehzahlermittlung*; BGHZ 194, 107 para 27 – *Polymerschaum I*.

28 The BGH's established judicial practice has emphasised this necessary consistency between the determination of the subject-matter of the patent claim in infringement proceedings and the determination of the same subject-matter in patent nullity proceedings, at least since a judgment of 7 November 2000 (X ZR 145/98, [2021] GRUR 232 (233) – *Brieflocher*); see in particular BGHZ 172, 108 para 13 – *Informationsübermittlungsverfahren I*: 'It is, however, correct … that the examination as to whether the subject-matter of the patent claim is patentable ... must relate to the technical teaching protected in the patent claim in its entirety and may not be limited to a part, such as the characterising features of a two-part patent claim (…). For the examination of this subject-matter, it is not sufficient to examine whether the wording of the patent claim can be read as referring to a prior art citation or a subject-matter suggested to the skilled person by the prior art. Rather, it is fundamentally necessary to first determine the subject-matter of the patent claim by interpreting the patent claim from the perspective of the skilled person addressed by the invention using the description and drawings. This applies to the examination of patentability in opposition or opposition appeal proceedings as well as to nullity proceedings (…) and infringement proceedings (…). Only when this interpretation has been made is the subject-matter of the subsequent examination of patentability determined.'

assessment of the infringement and validity of a European patent:

> 'This follows from the function of the patent claims, which under the European Patent Convention serve to define the scope of protection of the patent under Art. 69 EPC and thus the rights of the patent proprietor in the designated Contracting States under Art. 64 EPC, taking into account the conditions for patentability under Art. 52 to 57 EPC (…)'.[29]

This sentence is taken almost verbatim from the decision G 2/88 *Friction reducing additive/MOBIL OIL III* of the Enlarged Board of Appeal (EBA) of 11 December 1989[30] cited at the end. This is surprising at first, because the almost 35-year reception history of this decision has not prevented a passionate discussion in the case law of the Technical Boards of Appeal (TBA) about the conditions under which the description can and may be used to determine the subject-matter of the patent claim.[31]

Nevertheless, the quotation is not arbitrarily chosen, nor does the Court of Appeal, in order to bring the Boards of Appeal of the European Office on board by referring to a decision of the EBA, attribute to it a meaning that it does not have according to the context in which it stands. As is known, the referring TBA had asked the EBA whether a claim to the use of a compound for a particular non-medical purpose is novel for the purpose of Art. 54 EPC, having regard to a prior publication which discloses the use of that compound for a different non-medical purpose, so that the only novel feature in the claim is the purpose for which the compound is used.

The quoted sentence is preceded by a paragraph in which the EBA notes that Art. 84 EPC provides that the claims of a European patent application 'shall define the matter for which protection is sought'. Rule 29(1) EPC further requires that the claims 'shall define the matter for which protection is sought in terms of the technical features of the invention'. The primary aim of the wording used in a claim must therefore be to satisfy such requirements, having regard to the particular nature of the subject invention, and having regard also to the purpose of such claims.

When the EBA follows this up with the statement on the function of the patent claims to determine the scope of protection of the patent and thus the rights of the patentee, taking into account the requirements of patentability, it in fact draws the link between Art. 69 and 84 EPC and assigns to the patent claim the function of determining the subject-matter to be examined for patentability. It is for that subject-matter that, if it passes this examination, the exclusive right is granted, and it is for that subject-matter that the scope of protection – extending beyond that subject-matter and comprising equivalent embodiments – is to be determined in infringement proceedings.

It cannot be any other way, because otherwise the subject-matter of the exclusive right would be – or at least could be – different from what has been examined for patentability and may have to be re-examined in connection with an infringement dispute. This is not affected by the fact that the scope of protection of the patent (the determination of which is subject to separate rules not to be discussed here) is neither determined nor can be determined when the patent is granted. This is because the scope of protection of the patent is the scope of protection assigned to the subject-matter of the exclusive right and thus to the subject-matter for which patentability has been examined and affirmed. A scope of protection for a subject-matter other than that which has been placed under protection through the grant of the patent leads the patent system ad absurdum.

The UPCoA rightly refers not to the examination of infringement and patentability, but to the examination of infringement and *validity* of a European patent.[32] For even if it is not the patentability of the subject-matter of the patent claim that is to be examined, but rather the question of whether this subject-matter goes beyond that for which patent protection was applied and that was originally disclosed as an invention, i.e. the question of whether there is added matter (or the question of whether priority can be claimed for this subject-matter, which is to be examined in accordance with the same principles), the following applies: the subject-matter of the examination is one and the same subject-matter of the patent claim in each case.[33]

The following therefore applies to proceedings before the UPC, irrespective of whether the infringement of a patent or the examination of its validity is at issue: First, the patent claim whose subject-matter is at issue must be construed and interpreted with reference to the description.

The importance of this clarification can hardly be overestimated. Anyone observing the incipient practice of proceedings before the UPC will notice that in one and the same proceedings, the principles of interpretation of patent claims, which are well known to the practitioner from the case law of the Bundesgerichtshof, for instance, and which have just been taken to heart in the infringement discussion, are combined shortly afterwards – e.g. when presenting (alleged) added matter – with the use of decisions of the Boards of Appeal, which in this context in particular would accept little more than the wording of the texts used for comparison. It is the great advantage of the proceedings before the UPC that such a 'split of consciousness' can be prevented by a 'claim construction step'. This takes the same subject-matter as a basis in proceedings for provisional measures and in proceedings on the merits for the examination of validity and infringement. It is good that this was clarified as early as possible by the judgment of the Court of Appeal. Otherwise, the 'Angora cat phenomenon',[34] which the German dual-track ('bifurcated') system has been accused of fostering,

29 *10x Genomics v NanoString* (n 2) para 79.

30 OJ 1990, 93 [100], section 2.5. of the Reasons.

31 See Kemal Bengi-Akyürek, 'Anspruchsauslegung und Beschreibungsanpassung – wie weit darf man gehen?' [2023] GRUR Patent 110, with recent examples. In the opposition proceedings T 439/22, it is now expected that there will be a referral to the EBA on the correct approach to claim interpretation and the significance of the description in this context.

32 *10x Genomics v NanoString* (n 2) para 79.

33 See BGH, [2015] GRUR 868 para 25 – *Polymerschaum II*.

34 This refers to the patentee's tendency to 'puff up' the patent, ie to construe it broadly, when it is necessary to show an infringement by a contested embodiment, and to make the same patent small, ie to construe it narrowly, when it is necessary to defend its subject-matter as novel and inventive (see Jacob LJ in judgment of 19 March 2008, *European Central Bank v Document Security Systems Inc.* [2008] EWCA Civ 192: 'When validity is challenged, the patentee says his

would have celebrated a merry reign under the UPC unitary system.

2. The principles of claim interpretation

What are the principles of the interpretation of patent claims that should be applied in every case?

The Court of Appeal first states that the patent claim is not only the starting point, but also the decisive basis for determining the scope of protection of a European patent.[35] This leads to the substantive statements which are taken from Art. 1 of the Protocol on the Interpretation of Art. 69 EPC. They are transferred with slight modifications from the determination of the scope of protection to the interpretation of the patent claim.

The latter 'does not depend solely' on the strict, literal meaning of the wording used. The description and drawings are not only to be used to resolve any ambiguities in the patent claim, but 'must always be used as explanatory aids for the interpretation of the patent claim'[36] (based on Art. 1 sentence 1).

However, this does not mean that the patent claim merely serves as a guideline and that 'its subject-matter also extends to what, after examination of the description and the drawings, appears to be the subject-matter for which the patent proprietor seeks protection'.[37]

This wording, which is based on the second sentence of Art. 1 of the Protocol, initially appears to be a somewhat bold analogy to the principles of determining the scope of protection. They are meant to be distinct from an (alleged) earlier tendency in German jurisprudence to allow a scope of protection that is detached from the claim and derived (solely) from the description.[38] This 'extreme view', from which the interpretation protocol seeks to distance itself, did not concern the subject-matter of the patent claim, but rather the extension of the scope of protection to 'non-obvious' equivalents (*nicht-glatte Äquivalente*) and, in particular, a 'general inventive concept' (*allgemeiner Erfindungsgedanke*) extending more or less far beyond the subject-matter of the claim. Nevertheless, it also makes sense to point out for the interpretation of the patent claim that the wording of the patent claim is not a mere 'guideline'.

For the description may and must be used to construe the patent claim. This can lead to a different understanding than that conveyed by the wording of the patent claim in itself, even if the wording appears unambiguous. The (un)ambiguity of the wording is not a prerequisite for interpretation, but its result: unambiguous is the wording in which all aspects relevant to interpretation point in the same direction, in which only *one* interpretation is possible. In extreme cases – and really only in extreme cases – the interpretation requirement can lead to the wording of the claim being turned into its opposite.[39] Nevertheless, the following applies: If it is not possible to interpret the claim in a certain way taking into account the context resulting from the description, it is the claim and not the description that is decisive for determining the subject-matter of the patent claim. This is because the use of the description is a consideration of the context in which the patent claim stands, no different from the consideration of the context of the patent claim when interpreting an individual feature. Where such an interpretative context can no longer be established, the wording of the claim must prevail.[40]

The skilled person, who is the subject of the examination of the description and drawings in Art. 1 sentence 2 of the Protocol, is only mentioned by the Court of Appeal in the next paragraph, when it states:

> 'The patent claim is to be interpreted from the point of view of a person skilled in the art.'[41]

This makes it clear that it is not a matter of the patent claim being construed *by* a person skilled in the art, but rather of taking into account in the interpretation that the subject-matter of the patent claim is a technical teaching for the understanding of which the typical knowledge of persons skilled in the relevant art is important. This is particularly crucial in a court with legally and technically qualified members on the bench. Claim interpretation is an act of recognising and applying the law and therefore a genuinely legal task.[42] Judges with both legal and technical qualifications are appointed to this task because they are equal members of the panel. However, the technical judges are not appointed because they are the experts who have to interpret the patent claim,[43] but because they should be aware – in addition to the submissions of the parties – of what knowledge, concepts and experience are to be assumed for the persons skilled in the relevant art and are therefore to be taken into account, but not necessarily decisive, when interpreting the patent claim in the context of the description.[44]

The third sentence of Art. 1 of the Protocol, according to which Art. 69 EPC should be interpreted as defining 'a position between these extremes' and combine fair protection for the patentee with a reasonable degree of legal certainty for third parties, is modified by the Court of Appeal to the effect that 'in applying these principles' (i.e. to the interpretation of patent claims) the combination of adequate protection for the patentee with sufficient legal

patent is very small: the cat with its fur smoothed down, cuddly and sleepy. But when the patentee goes on the attack, the fur bristles, the cat is twice the size with teeth bared and eyes ablaze'. The defendant in infringement proceedings and the claimant in revocation proceedings generally take the opposite view, see Peter Meier-Beck, 'Der gerichtliche Sachverständige im Patentprozeß' in *Festschrift 50 Jahre Bundespatentgericht* (Heymanns 2011) 403 (408 f).

35 *10x Genomics v NanoString* (n 2) para 74; see BGHZ 98, 12 (18) – *Formstein*.

36 *10x Genomics v NanoString* (n 2) para 75.

37 ibid para 76.

38 This is one of the 'extremes' mentioned in the following sentence of the interpretation protocol, which is countered by the (supposed) English tendency to adhere strictly to the wording of the claim and not to allow any extension of the scope of protection beyond this wording.

39 BGH, [2015] GRUR 875 para 32 – *Rotorelemente*.

40 BGHZ 189, 330 para 23 – *Okklusionsvorrichtung*; *Rotorelemente* (n 39) para 16; BGH, [2015] GRUR 897 para 22 – *Kreuzgestänge*.

41 *10x Genomics v NanoString* (n 2) para 77.

42 cf only BGHZ 160, 204 (212 f) – *Bodenseitige Vereinzelungseinrichtung*; BGHZ 171, 120 para 18 – *Kettenradanordnung I*.

43 The comment by Christoph Schröder, Hannes Jacobsen and Paul Szynka, 'Die „ausreichend sichere Überzeugung von der Ungültigkeit des Patents" – Zum Rechtsbestand im Verfügungsverfahren vor dem EPG und anderen Fragen nach der ersten materiellen Entscheidung des Berufungsgerichts – 10xGenomics II' [2024] GRUR Patent 138 para 12, that it follows from the fact that the skilled person 'forms the standard of interpretation' that the mere wording is not decisive, is therefore not unobjectionable.

44 cf *Kettenradanordnung I* (n 42) paras 18 f.

certainty for third parties should be achieved (or at least sought).[45] The Court of Appeal thus adopts an understanding of the third sentence of Art. 1 which rejects the unrealistic idea, nourished by the wording of the provision, that there is an interpretation method which is per se suitable for precisely balancing fair protection for the patentee with a reasonable degree of legal certainty in each individual case. It is replaced by a mere aim to guide the application of the outlined principles of interpretation.

3. Claim interpretation in the case at hand

On the merits, the Court of Appeal initially agrees with the first instance that a cell or tissue sample within the meaning of patent claim 1 is to be understood as a sample that is still structurally recognisable as a cell or tissue.[46]

Although this is justified with reference to the description,[47] this interpretation does not seem to me to be completely compelling. This is because, as the Court of Appeal does not fail to recognise, the statements quoted in the description tend to point in the opposite direction. According to the Court of Appeal, the understanding of the first instance is supported by the wording of the claim, which distinguishes between the plurality of analytes to be detected and the cell or tissue sample, so that the two cannot be identical. Although the analytes are part of the cell or tissue sample, the latter must still be *structurally recognisable* as such.[48] This is not contradicted by the fact that various types of sample treatment are mentioned in the description in paras. 48 and 49, including, in addition to those in which the cell or tissue sample remains intact, those in which proteins or nucleic acids are isolated from a cell or tissue sample, separated electrophoretically on a separation medium and then applied to a blotting membrane (para. 49, sentence 2). According to the Court of Appeal, the mere mention in the description does not imply that those proteins or nucleic acids are to be regarded as analytes in a cell or tissue sample even after they have been treated as just described.[49]

This interpretation would be beyond any doubt if the cell or tissue structure were of relevance for the method according to the invention or its result. But is this the case? The description, which only uses the term 'sample' and not the term 'cell or tissue sample', which was only added to the claim by the divisional application, expressly states that a target molecule or analyte can be both part of a sample and its sole component (para. 211, first sentence, not mentioned by the Court of Appeal). If the claim-appropriate addition '*cell or tissue*' is inserted at this point, the sentence reads:

> 'A target molecule or an analyte can be part of a cell or tissue sample that contains other components or can be the sole or major component of the sample.'

One may argue, in agreement with the CFI, that nowhere does it say that such a sample limited to the extracted analyte is still a cell or tissue sample (and one may therefore read para. 211 as above),[50] and the Court of Appeal argues similarly with regard to para. 49 of the description.[51] However, in my opinion, this would only be really convincing if the preservation of the structural information of the cell or tissue were in any way relevant to the invention, so that what is said in para. 211 about samples in general cannot apply to cell and tissue samples, namely that the target molecule (the analyte) may be part of the sample, but may also be its only component. However, this cannot be recognised.[52] It therefore seems doubtful to me whether a function-oriented interpretation can justify reading the addition 'cell or tissue' to sample not only as a specification of the origin of the sample (which is arbitrary according to the description)[53] that limits the subject-matter of the patent in suit in relation to the broader disclosure, but also as a specification which limits the cell or tissue samples according to the claim to those which are not only obtained from cells or tissue, but which still reveal the cell or tissue structure.[54]

This point is not decisive for the outcome of the appeal judgment. I mention it in the context of this consideration only because it exemplifies the opposite poles of the interpretation at issue. On the one hand, there is the wording of the claim with the juxtaposition of cell and tissue sample and the analyte in such a sample, and it is quite clear that it is precisely the structure or the structural information that, if one abstracts these terms, distinguishes one from the other from a technical point of view. On the other hand, there is the context in which this terminology is used, i.e. the description, which says that the analyte can be a component of the sample, but also the only component of it, and does not deal with the spatial localisation of the analyte in the sample. There is no patent remedy for resolving such conflicts. But everything can depend on the resolution of this conflict, and the only

45 *10x Genomics v NanoString* (n 2) para 78.

46 ibid para 80.

47 ibid paras 81-84.

48 ibid para 81.

49 ibid para 83.

50 LD Munich, [2023] GRUR 1513 para 134.

51 *10x Genomics v NanoString* (n 2) para 83.

52 The Court of Appeal mentions this indirectly at a later point when it states that 10x Genomics' objection that there was no sufficient expectation of success from a technical point of view because the skilled person would have been confronted with problems such as 'molecular crowding' (distinguishability of several analytes occurring in close proximity) or 'autofluorescence' (unpredictable interactions) in the cell or tissue sample, cannot be accepted. In this respect, these are problems that regularly arise in connection with the in situ detection of analytes in tissue or cell samples, and this assessment is supported by the fact that the patent in suit does not provide any information on how to deal with these problems in in situ detection (*10x Genomics v NanoString* (n 2) para 112).

53 According to para 9, a 'sample amenable to the methods described herein … may be a sample from any sources, e.g., but not limited to biological samples, e.g., collected from organisms, animals or subjects, environmental samples, food, food byproduct, soil, archaeological samples, extraterrestrial samples, or any combinations thereof'.

54 In this context, the statements in the Order of the Federal Patent Court (BPatG) of 7 February 2023, cited by the Court of Appeal in another context, which the BPatG issued in proceedings relating to another patent based on the same parent application (3 Ni 20/22 [EP]), are also enlightening. There, the BPatG states (at 6.2) that.the defendant's argument that according to D6 the ASMs are arranged purely randomly on the carrier and thus the spatial information from the genomic DNA sample has been lost may be correct. However, there is no indication in the granted patent claim 1 that, in addition to a temporal assignment of signals to individual analytes, *a spatial localisation of the analytes in the sample* should also take place (emphasis mine). This is also true for claim 1 of the patent in suit, irrespective of the addition of 'cell or tissue' to the sample.The question then arises as to why the skilled person should assume, despite the statements to the contrary in the description, that the patent in suit nevertheless requires the preservation of contextual (spatial) information in the cell or tissue sample, which is not relevant for the method according to the invention.

thing that helps is the careful and complete analysis of all the details that can shed light on the correct understanding of the claim.

While the Court of Appeal agrees with the LD in its understanding of the term cell or tissue sample, it contradicts the LD in the – incidental and not further substantiated – assumption that the detection reagents must remain bound to the respective analytes during the entire detection procedure according to feature group 4.[55] It is true that the detection reagents must bind securely to the respective analytes and therefore a sufficient incubation period must be provided (feature 3). Contrary to the opinion of the CFI, however, the necessity of a sufficient incubation period does not preclude the possibility that the decoder samples, once they have entered into a secure bond with the respective analytes, can be removed at a later point in time, for example together with the removal of the signal signatures provided for in feature 4.3, and replaced again with the same detection reagents.[56]

Thus, neither the wording of the patent claim nor the description, neither common general knowledge nor functional considerations, provided any basis for the restrictive interpretation with which the LD had justified a further difference to prior art.[57] It was therefore excluded.[58]

III. The assessment of patentability

In addition to the statements on the interpretation of the patent claim and the necessity of such an interpretation, section 5 of the Reasons is of decisive importance for the outcome of the appeal proceedings. In this section, the Court of Appeal explains why 'the validity of the patent at issue is not established with a sufficient degree of certainty for the injunction requested to be issued'.[59]

1. Standard of a sufficient degree of certainty

In the introductory subsection a, the Court of Appeal first agrees with the LD, with reference to Rule 211.2 RoP, that a provisional measure requires 'reasonable evidence to satisfy the court to a sufficient degree of certainty' that the necessary conditions are met. Such a sufficient degree of certainty is lacking if the court considers it to be predominantly probable that the patent is invalid. The burden of presentation and proof for facts relating to the lack of validity of the patent and other circumstances supporting its position lies with the defendant.[60]

The Court of Appeal leaves no doubt that it is not a question of whether the CFI considers it predominantly probable that the subject-matter of the patent lacks patentability or that the patent is invalid for other reasons. Rather, the Court of Appeal subjects the CFI judgment to a complete review. The first sentence of the second subsection b reads:

> 'Contrary to the opinion of the CFI, in the judgment of the Court of Appeal it is, on the balance of probability, more likely than not that the subject-matter of claim 1 in the version asserted in the main request will prove to be not patentable'.[61]

The standard of preponderant probability, which the LD had spent considerable effort to justify, is – just as in the LD's decision – hardly brought to life. Nor does it seem to me to be of much use.[62] The standard of preponderance of probability can be used in the evaluation of evidence (is factual variant A more probable than variant B?). It can also be used in forecasting decisions (is factual scenario A more likely than scenario B?).[63] However, the validity of the patent is usually neither one nor the other. Rather, the facts of the case are generally established: they consist of the patent, its application and the prior art documents, which are generally not in dispute as to whether they form part of prior art.[64] They must be (legally) examined to determine which conclusions can be drawn from their respective disclosures. These conclusions can – as our case shows – be right or wrong or more or less certain or doubtful. However, it will not be possible to formulate a standard of probability for this judgment any more than for the question of whether a decision will be upheld on appeal. Ultimately, all that remains of the standard of sufficient certainty is an appeal to be aware of the fact that mistakes can be made when assessing the validity of a patent in court proceedings and that the risk of an erroneous judgment is even greater in preliminary proceedings, where both the parties and the court have less time to develop and discuss the arguments than in proceedings on the merits,[65] which is why an overly hasty approach to complex and complicated issues should be avoided. Effective legal protection for patentees should not be used as an argument against this. After all, the hasty enforcement of patents which, on closer inspection, turn out to be invalid does neither the parties nor the patent system as a whole any favours.

What does the Court of Appeal's own examination of the (probable) validity of the patent in suit look like?

55 *10x Genomics v NanoString* (n 2) para 85.

56 ibid para 86.

57 ibid paras 87 f.

58 A different view is apparently taken by Matthias Leistner, 'Die erste substanzielle Entscheidung des EPG-Berufungsgerichts. Auslegung der Patentansprüche, Neuheit und Naheliegen, Anforderungen für einstweilige Anordnungen. (Zugleich Anmerkung zu EPG, Anordnung v. 26.02.2024 – UPC_CoA_335/2023 – NanoString Technologies u.a../. 10x Genomics u.a.)' [2024] GRUR 514 (515), who – albeit like the LD without further justification – believes that the result of the Court of Appeal is debatable. It is a 'borderline case'; 'patent claim 1 is not unambiguous on this issue'.

59 *10x Genomics v NanoString* (n 2) para 89.

60 ibid paras 91-93.

61 ibid para 95.

62 Different opinion, Schröder, Jacobsen and Szynka (n 43) 138 paras 22-33; similar to here, however, Leistner (n 4) 1578 (1584) with the remark that it is more decisive than quibbling over words when formulating the standard of probability that the court carefully deals with the question of the patent's prospects of survival and forms a well-founded, independent conviction in this respect; cf also Marcus Grosch, 'Provisional injunctions in the UPC and the sufficient degree of certainty regarding validity' [2023] GRUR Patent 25 para 18, Peter Meier-Beck, 'Die Prüfung der Rechtsbeständigkeit des Patents im Verfahren des einstweiligen Rechtsschutzes wegen Patentverletzung' [2023] GRUR 603 (607).

63 In connection with the review of the validity of a patent, such a prognosis is at most a matter of pending opposition proceedings or in the German dual system, in which the infringement court must attempt to anticipate the probable decision of another court in the patent revocation proceedings, cf Schröder, Jacobsen and Szynka (n 43) 11 para 4.

64 An exception to this is situations in which the legal validity of the patent depends on whether an alleged prior public use can be proven or not.

65 cf Schröder, Jacobsen and Szynka (n 43) 11 paras 24-27.

2. The novelty test

The Court of Appeal first rejects the argument that D6 is prejudicial to novelty.[66] This is a consequence of the interpretation of the term 'cell or tissue sample', since D6 analyses amplified DNA molecules. Nevertheless, the Court of Appeal first describes the content of D6 in relative detail,[67] in order to draw the conclusion from this that all other features of patent claim 1 are disclosed there.[68] This also lays a solid foundation for the subsequent discussion of inventive step.

The detailed explanation of the content of D6 is also very welcome because this is not always the case in opposition and revocation proceedings. Rather, sentences and half-sentences of a prior art document in which features of the invention according to the patent in suit are actually or allegedly disclosed are often selectively 'picked out'. These sentences can be scattered throughout the document. On the one hand, this practice has the disadvantage that it does not really facilitate the understanding of the document by a non-technically trained lawyer. On the other hand, and above all, it also has the disadvantage that the context of those quotes can be lost. However, interpretation in context is just as important for prior art documents as it is for the patent in suit.[69] It is not – as in the case of the patent in suit – a matter of interpreting the patent claim in the context of the description of the invention in the patent specification. This is because when it comes to the prior art, it is only the disclosure that matters and not the distinction between claim and description. However, as with any other document, the meaning of a word or phrase or paragraph may depend on the context.

It is particularly important to keep this in mind because the more features of the patent claim it discloses, the more interesting the document becomes. In any case, the claimant in revocation proceedings reads it with the intention of not missing any feature of the patent claim that can be found there. This can lead to a feature being 'found' in a document that an unbiased reader would not have found there. The Bundesgerichtshof has expressed this in such a way that the context of the citation is replaced by the context of the later invention, which determines what is sought in the prior art.[70] Finally, inadequate consideration of the context of a citation can also lead, conversely, to different facts being erroneously inferred from different terminology, or to the factual proximity to the subject-matter of the patent in suit not being correctly recognised.[71] In this respect too, a careful analysis of the overall disclosure of a piece of prior art, as undertaken by the Court of Appeal, can protect the practitioner from erroneous conclusions when assessing novelty or inventive step – in one direction or the other.

3. The problem underlying the invention

Since no other piece of prior art could be considered as prejudicial to novelty, the Court of Appeal then turns to inventive step. Unlike the LD, the Court of Appeal considers it 'more likely than not' that the subject-matter of claim 1 will prove to be obvious.[72]

The considerations made by the Court of Appeal in this regard are introduced by the sentence:

> 'D6 would have been of interest to a person skilled in the art who, at the priority date of the patent at issue, was seeking to develop high-throughput optical multiplexing methods for detecting target molecules in a sample …'.[73]

Thus, the Court of Appeal does not identify a 'closest piece of prior art' in order to then derive the problem to be solved from the difference to be overcome by adding or modifying those features by which the patent in suit differs from the previously identified closest prior art,[74] but simply starts from the problem that it had taken from the patent in suit itself when construing the patent claim.

This should neither be interpreted as a general rejection of the 'problem-solution approach' as practised by the EPO and its Boards of Appeal, nor as a statement on the relevance of the problem stated in the patent itself for the examination of obviousness. Both approaches can be useful in the examination of inventive step and lead to appropriate results. However, both approaches can also lead to artificial starting points for this examination and thus to inappropriate results.

If the patent specification states a problem – which is not always the case – it is usually formulated by the applicant. It may reflect a problem that was actually faced by the skilled person or the applicant at priority date, and was solved by the invention. However, it can also – in an endeavour to emphasise the inventor's achievement or perhaps to make it appear greater than it actually is – formulate a problem which, chosen as a starting point, leads to hurdles for the skilled person which they would not have to overcome if they were travelling along a different path or to a different destination. According to the judicial practice of the Bundesgerichtshof, the problem is in any case to be derived from what the invention actually achieves,[75] and therefore does not necessarily correspond to what is said in the patent specification about the problem underlying the invention. This also seems to be the approach of the Court of Appeal, which autonomously formulates the problem with reference to the strong need mentioned in the description (para. 6) for precise and sensitive methods with high throughput for the detection, identification or quantification of target molecules in a sample, e.g. in complex mixtures.[76] As part of the

66 *10x Genomics v NanoString* (n 2) para 97.

67 ibid paras 98-101.

68 ibid para 102.

69 See already BGHZ 179, 168 para 25 – *Olanzapin*: 'The assessment of whether the subject-matter of a patent has been affected by a prior publication to the detriment of novelty requires the determination of the overall content of the prior publication.'

70 BGH, [2019] GRUR 925 para 18 – *Bitratenreduktion II*.

71 cf *Polymerschaum I* (n 27).

72 *10x Genomics v NanoString* (n 2) para 105.

73 ibid 527 para 106.

74 In view of the reference to the closest prior art (LD Munich, [2023] GRUR 1513 para 179), this would have been expected from the judgment of the LD, which, however, does not do so either.

75 BGHZ 98, 12 (20) – *Formstein*; BGH, [2010] GRUR 602 (605) – *Gelenkanordnung*; BGH, [2012] GRUR 803 para 31 – *Calcipotriol-Monohydrat*.

76 *10x Genomics v NanoString* (n 2) para 70. No mention is made of the fact that the sample is a cell or tissue sample according to the claim, which is in some contrast to the importance that the Court of Appeal attaches to the presence of a cell or tissue structure.

interpretation of the patent claim, the formulation of the underlying problem is, of course, bound to the content of the patent specification.[77] Therefore, it cannot guarantee in every case that a 'remote' problem set out in the description is replaced by one that is more plausible for the skilled person at priority date.

Similarly, the problem of overcoming a difference may reflect actual disadvantages of a device known in the prior art for a particular purpose or of a method applicable thereto, which make it plausible for the skilled person to search for a better solution. However, focussing on the – necessarily *ex post* identified – differences to the patent in suit can also create an artificial problem that no skilled person would have dealt with at the priority date.[78]

According to the law, the affirmation or denial of inventive step depends solely on whether the technical teaching of the invention was obvious to a person skilled in the art. Article 56 EPC does not require that the invention was obvious to a person skilled in the art who wanted to solve a specific technical problem caused by a specific piece of prior art. It is irrelevant that it was not obvious to solve problem A by means of the invention if the same invention (the same technical teaching) was the obvious solution to problem B.[79] This is the reason why, for example, a surprising effect of a combination of active agents cannot constitute an inventive step if it was obvious to the skilled person for other reasons to combine the active agents in question and the surprising effect is thus a mere 'bonus effect'.[80]

Therefore, the starting point of the person skilled in the art requires justification which, as the Bundesgerichtshof formulates, usually lies in the endeavour of the skilled person to find a better solution for a specific purpose than that provided by prior art.[81]However, it is not worth thinking about the closest piece of prior art if – as in our case – there is at least one plausible starting point from which the skilled person arrives at the teaching according to the invention in an obvious manner. It is then irrelevant whether there is another possible starting point and whether this is perhaps even closer to the invention. Many roads lead to Rome, and this can also be the case with an invention.[82]

The Court of Appeal justified the fact that D6 was of interest to the skilled person with the method disclosed therein for detecting a large number of amplified single molecules (ASMs) by encoding and decoding the single molecules, in which the encoding is carried out by the probe-mediated generation of ring-shaped DNA and the decoding by sequential temporal detection of the targeted ASMs. Since at the time of priority there was a need for multiplex analysis techniques, especially for test samples, the skilled person had reason to consider whether the encoding and decoding method disclosed in D6 for ASMs arranged *in vitro* in an array format could be transferred to the detection of ASMs in cell or tissue samples.[83] Thus, there is a plausible reason for the skilled person to address D6, and this suffices.

4. The obviousness of the solution

In doing so, the Court of Appeal not only set the starting point, but at the same time took at least the first step towards affirming the obviousness of the invention.[84] This is because the solution according to the invention to the problem of transferring the encoding and decoding method disclosed in D6 for ASMs arranged *in vitro* in an array format to the detection of analytes in cell or tissue samples is: the detection of analytes in cell or tissue samples using the encoding and decoding method disclosed in D6. In other words, the patent in suit does not teach *how* the prior art method can be applied to cell or tissue samples, but only *that* it is applied to them. The skilled person therefore only had to answer the question of whether such a transfer was reasonable and possible or whether its realisability could at least be expected with a reasonable degree of certainty or probability.

By emphasising this, the Court of Appeal illustrates the central importance of carefully examining the question of whether there is at least one plausible task and a plausible starting point from which the teaching according to the invention was obvious. Nothing demonstrates this more impressively than the contrast with the decision at first instance. The LD does not even go as far as examining a starting point for the skilled person. Instead, its decision states that the skilled person would not have used D6 'as a realistic starting point, let alone as the closest prior art, in view of the problem underlying the patent'. The document was not directed to the detection of a large number of analytes in a cell or tissue sample. It does disclose an 'encoding and decoding method' similar to that used in the patent in suit, but in a completely different context, namely ASMs on an array. A person skilled in the art would not 'transport' this method to a cell or tissue sample (mounted on a solid support) without hindsight. The LD is convinced that no motivation for such a transport has been presented.[85] The feature that establishes novelty – also according to the judgment of the Court of Appeal – is thus used here to reject highly relevant prior art because of this (single) difference as the starting point of the skilled person without even addressing the question of the obviousness of the invention.[86]

77 *Gelenkanordnung* (n 75); *Calcipotriol-Monohydrat* (n 75) para 31.

78 See BGH, [2015] GRUR 352 para 17 – *Quetiapin*; BGH, [2017] GRUR 498 paras 28 f – *Gestricktes Schuhoberteil*; BGH, [2018] GRUR 509 paras 102-04 – *Spinfrequenz*.

79 BGH, [2023] GRUR 693 (695) – *Hochdruckreiniger*; BGH, [2011] GRUR 607 (609) – *Kosmetisches Sonnenschutzmittel III*; *Quetiapin* (n 78) para 13.

80 BGH, [2003] GRUR 317 (320 f) – *Kosmetisches Sonnenschutzmittel I*. See also BGH, [2019] GRUR 157 para 38 – *Rifaximin* α.

81 *Olanzapin* (n 69) para 51.

82 See BGH, [2015] GRUR 356 para 31 – *Repaglinid*.

83 *10x Genomics v NanoString* (n 2) paras 106 f.

84 Schröder, Jacobsen and Szynka (n 43) 138 para 43 are of the opinion that a differentiation between suggestion and technical problem 'cannot be clearly inferred' from the decision of the Court of Appeal at this point.

85 LD Munich, [2023] GRUR 1513 para 189.

86 By stating that the skilled person would not have used D6 'as a realistic starting point, let alone as the closest prior art, in view of the problem underlying the patent', the closest prior art to be determined according to EPO practice on the basis of objective criteria (*ex post*) becomes a subjective *ex ante* criterion of a skilled person looking for promising starting points, whereby it remains completely open and undiscussed by the LD what this skilled person is actually looking for and what could or could not be promising for him or her and for what reasons. Following the same pattern, the judgment of the LD also states that the 'thesis' of the NanoString party expert, which amounts to the fact that the person skilled in the art would have no insurmountable objections to the

It is not surprising that the Court of Appeal answers the question as to whether the skilled person is prompted to turn to the transfer from *in vitro* to *in situ* with a clear yes, irrespective of the relativisation as 'predominantly probable'. This is because it justifies the suggestion to 'think in this direction' by referring to a reference in D6 to the fact that rolling-circle ASMs have already been used in the prior art for reading out various genotyping assays and for detecting proteins and protein complexes *in situ*, as well as to a similar reference in the further piece of prior art B30.[87]

In this situation, an inventive step according to generally recognised principles could only have been affirmed if the skilled person had reason to assume that the transfer of the disclosed *in vitro* method for ASMs to *in situ* analysis, which in itself appeared desirable, would probably not be possible or could only be realised by overcoming considerable obstacles; in other words, there would have been a lack of sufficient expectation of success[88] for the attempt at transfer.

The lack of a sufficient expectation of success is clearly denied by the Court of Appeal. It may be assumed, in agreement with 10x Genomics, that various probes and methods for the production of ASMs were known, the suitability of which for *in situ* application was different, and the skilled person would not have readily concluded from the successful application of a probe *in vitro* that this probe would also work in an *in situ* context. However, this aspect did not prevent the authors of B30 from transferring it, nor is it apparent why this would have been different based on the detection method carried out in D6 with selector probes *in vitro*.[89] These are problems that regularly arise in connection with the *in situ* detection of analytes in tissue or cell samples, which skilled persons were able to deal with and which therefore did not prevent them from carrying out corresponding experiments.[90] Finally, the Court of Appeal states that this assessment is also supported by the fact that the patent in suit does not contain any explanations as to how the problems mentioned are to be solved in the case of *in situ* detection.[91] It thus points out that the method of transfer is addressed neither in the claim nor even in the description of the patent in suit.

When these considerations are characterised by Leistner as 'undoubtedly normative assessments made to the effect that certain existing technical hurdles and resulting concerns with regard to transferability … are not considered sufficient with regard to an inventive step' and this leads to a 'certain (unavoidable?) unpredictability of the standard',[92] this gives a skewed picture. Of course, the requirement of a reasonable expectation of success for the obviousness of a certain technical solution as such constitutes a normative criterion. It also requires a judicial assessment simply because of the attribute of 'reasonable' expectation of success; the Federal Court of Justice (Bundesgerichtshof) emphasises that the requirements cannot be formulated in a generally applicable manner, but must be determined in each individual case, taking into account the technical field in question, the extent of the incentive for the skilled person, the effort required to adopt and pursue a specific approach and any alternatives that may be considered, as well as their respective advantages and disadvantages.[93] However, it is also a 'normative' criterion not to ask about the specific expectation of success. The divergence between the Court of Appeal and the CFI is not based on a normative assessment of the technical facts first introduced by the Court of Appeal. It is based – not unlike most divergences in the examination of inventive step – on the fulfilment of this criterion in the individual case, which the Court of Appeal elaborates and which the CFI did not elaborate. The fact that the result of the Court of Appeal deviated from that of the first instance was more or less 'unavoidable' only because only the second instance carefully worked out the skilled person's specific expectation of success in the case to be decided.

5. Assessment of the amended claim's validity

This could have been the end of the appeal judgment. However, the Court of Appeal goes one step further and also discusses and answers in the negative the question of whether the issuance of an interim injunction can be justified on the basis of the auxiliary request filed at first instance. It leaves open the admissibility of this request – which is by no means obvious – because it is also unfounded in any case. Even the amended patent claim is unlikely to prove valid.[94] Since these details of the Reasons for the decision are of no further value for our purposes, I will not go into them further.

IV. A brief summary

The decision of the Court of Appeal certainly does not answer all questions concerning the interpretation of a

application of the teaching of D6 to a cell or tissue sample (and thus would see a 'very high expectation of success'), is based 'on an *ex post facto* analysis with knowledge of the invention'; even if one wanted to follow this, 'it does not follow without further ado that the skilled person would actually have done this, which would, however, be necessary to establish a lack of inventive step' (LD Munich, [2023] GRUR 1513 para 192). Whether the disqualification of the high expectation of success assumed by the expert – in agreement with the Court of Appeal – as 'retrospective' should mean that the expectation of success was low in the opinion of the LD in *ex ante* consideration remains open, as does the question of the reasons for such an assumption. 'To be on the safe side', the motivation ('would actually have done') is added as an *further* hurdle in the event that a high expectation of success – which should actually be sufficient motivation for the skilled person to undertake to verify the presumably verifiable expectation – should nevertheless be affirmed. This use of methodological set pieces unintentionally illuminates how little can be gained from the criteria of a 'preponderant probability' of validity and the 'sufficient degree of certainty' of the adjudicating body.

87 *10x Genomics v NanoString* (n 2) para 108 f. The latter is the article of Magnus Stougaard and others. 'In situ detection of non-polyadenylated RNA molecules using Turtle Probes and target primed rolling circle PRINS' (2007) 7 BMC Biotechnology 69.

88 See on this criterion only EPO-TBA, OJ 1982, 268 = [1992] GRUR Int 771 (775) – *Fusionsproteine/HARVARD*; Swiss Federal Supreme Court, [1996] GRUR Int 1059 (1063) – *Manzana II*; BGH, [2012] GRUR 803 para 46 – *Calcipotriolmonohydrat*; BGH, [2019] GRUR 1032 para 31 – *Fulvestrant*; BGH, [2020] GRUR 2020, 1178 para 108 – *Pemetrexed II*.

89 *10x Genomics v NanoString* (n 2) para 110.

90 Schröder, Jacobsen and Szynka (n 43) 138 para 47 correctly point out that the Court of Appeal does not define common general knowledge in this context. The usual practice in English proceedings of first presenting the common general knowledge in detail before the actual examination of the invention for patentability is therefore probably not recommended for proceedings before the UPC.

91 *10x Genomics v NanoString* (n 2) para 112.

92 Leistner (n 58) 514 (516).

93 *Fulvestrant* (n 88) 1032 para 31.

94 *10x Genomics v NanoString* (n 2) paras 115-22.

patent in the infringement and validity examination and the methods and criteria of the examination of patentability and, in particular, inventive step, which may be of decisive importance in the individual case – as the dispute teaches, in particular in the contrast between the first and second instance decisions. Instead, the decision of the Court of Appeal largely avoids abstract statements on the major issues and instead takes an exemplary approach in an admirably simple form. However, this should not obscure the clear general statements that nevertheless lie in the judgment of the specific dispute.

The casual reader might be inclined to see the decisive factor of general importance in the general statements in section 4 d aa of the Reasons, which were also included in the guiding principles on the interpretation of patent claims. However, this would be a gross oversimplification. At least as important as the statement that the principles of interpretation of patent claims are to be observed not only in the examination of infringement but also in the examination of validity, where the same subject-matter of the patent forms the reference point, are the – partly implicit – statements on interpretation and on the examination of inventive step to which no guiding principle is devoted. I would like to summarise them in the following seven commandments, without claiming to be exhaustive:

1. Always interpret the features of the claim in the context of this claim and the claim in the context of the description, for whatever reason its subject-matter interests you. Consider the usual technical understanding of a term, but do not jump to conclusions.
2. Resist the inner Angora cat and do not interpret the patent claim according to the consequences resulting from the understanding of a feature or the assumption of an implicit feature for validity or infringement.
3. Also read each piece of prior art in its own context first. Resist the temptation to read into a document what you know from the patent in suit, but also do not jump to conclusions from different terms.
4. Try to avoid an *ex post* view, but always be aware that you are necessarily an *ex post* viewer.
5. Carefully examine each piece of prior art put forward by the opponent to see whether it represents a plausible starting point from which the skilled person would have arrived at the invention in an obvious way.
6. Remember that different problems to be solved can mean different paths with different hurdles to the same goal.
7. Argue with the concrete facts of the case and avoid buzzwords.