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Datasheet for the decision of 23 March 2023

Case Number: G 0002/21

Appeal Number: T 0116/18 – 3.3.02

Application Number: 12002626.5

Publication Number: 2484209

IPC: A01N43/56, A01N51/00

Language of the proceedings: EN

Title of invention:
Insecticide compositions

Patent Proprietor:
Sumitomo Chemical Company, Limited

Opponent:
Syngenta Limited

Headword:
Reliance on a purported technical effect for inventive step (plausibility)

Relevant legal provisions:

EPC Art. 52(1), 54, 56, 83, 100, 101(2), 106(1), 112(1)(a), 112(2), 113(1), 117, 125
EPC R. 4, 117-124, 150
RPEBA Art. 9, 10, 13, 14(2)
RPBA 2020 Art. 22

Law of the Contracting States:

Switzerland
Code of Civil Procedure (Zivilprozessordnung), Art. 157
Federal Act on the Federal Patent Court - Patent Court Act (Bundesgesetz über das Bundespatentgericht – Patentgerichtsgesetz), Art. 27

Germany
Patent Act (Patentgesetz), § 93(1)
Code of Civil Procedure (Zivilprozessordnung), § 286

The Netherlands
Dutch Code of Civil Procedure (Wetboek van Burgerlijke Rechtsvordering), Art. 152(2)

Keyword:

"admissibility of referrals" – yes
"re-phrasing of the referred questions" – no
"extending the scope of the referred questions" - no
"principle of free evaluation of evidence" – "exception to the principle required" – no
"inventive step" - "reliance on technical effect" – yes, based on the application as originally filed

Decisions cited:

G 0003/97, G 0004/97, G 0002/08, G 0002/10, G 0001/12, G 0001/13, G 0003/14, G 0001/19, G 0003/19, G 0001/21, T 0390/88, T 0482/89, T 0838/92, T 0939/92, T 0798/93, T 0543/95, T 0558/95, T 0142/97, T 0592/98, T 0278/00,

T 0329/02, T 0609/02, T 0893/02, T 0972/02, T 1110/03, T 0474/04, T 1329/04, T 0578/06, T 1599/06, T 0536/07, T 1437/07, T 1642/07, T 0545/08, T 1545/08, T 0108/09, T 1797/09, T 0266/10, T 0415/11, T 0754/11, T 1677/11, T 1791/11, T 0125/12, T 0419/12, T 0760/12, T 0863/12, T 2294/12, T 0235/13, T 0895/13, T 1045/13, T 1285/13, T 2059/13, T 2348/13, T 2371/13, T 0787/14, T 0887/14, T 1363/14, T 0321/15, T 0919/15, T 2097/15, T 2238/15, T 0179/16, T 0184/16, T 0488/16, T 0517/16, T 0578/16, T 0978/16, T 1499/16, T 2730/16, T 0229/17, T 1322/17, T 1680/17, T 2200/17, T 0031/18, T 0116/18, T 0122/18, T 0334/18, T 0377/18, T 0391/18, T 1306/18, T 1442/18, T 2923/18, T 1099/19, T 1343/19, T 1571/19, T 2029/19, T 2963/19, T 3109/19, T 2015/20

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- 3 Ni 20/15 - Erlotinib hydrochloride

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Cour de cassation
- 15-19726 - Merck c/ Teva

Tribunal de Grande Instance de Paris
- 07/16446 – Teva / Sepracor
- 16/01225 - Ethypharm / MSD

The Netherlands
Gerechtshof Den Haag
- 200.195.459/01 - Leo Pharma v Sandoz
- 200.237.828/01 - Astrazeneca v Sandoz

Rechtsbank Den Haag
- C/09/627925 / KG ZA 22-326 – Bristol-Myers Squibb Holdings Ireland v Sandoz

United Kingdom
UK Supreme Court
- Generics (UK) (trading as Mylan) v. Warner-Lambert Company Ltd. [2018] UKSC 56

England and Wales Court of Appeal
- Mölnlycke v Procter & Gamble [1994] R.P.C. 49
- Schlumberger v EGMS [2010] EWCA Civ 819
- Warner-Lambert Company LLC v Generics (UK) Ltd (trading as Mylan) and others [2016] EWCA Civ 1006
- Illumina Cambridge Ltd v Latvia MGI Tech SIA and others [2021] EWCA Civ 1924
- FibroGen Inc. v Akebia Therapeutics Inc. and another company; Astellas Pharma Inc. v Akebia Therapeutics Inc. and other companies [2021] EWCA Civ 1279

England and Wales High Court, Patents Court
- Actavis Group PTC EHF & Anr v Eli Lilly & Co [2015] EWHC 3294 (Pat)
- Accord v Medac [2016] EWHC 24 (Pat)
- Hospira UK Ltd, v Cubist Pharmaceuticals Ltd [2016] EWHC 1285 (Pat)
- Positec Power Tools Europe Ltd v Husqvarna AB [2016] EWHC 1061 (Pat)
- Generics (UK) Ltd trading as Mylan and another v Yeda Research and Development Company [2017] EWHC 2629 (Pat)
- Cantel Medical (UK) Ltd v Arc Medical Design Ltd [2018] EWHC 345 (Pat)
- Eli Lilly and Co and other companies v Genentech, Inc [2019] EWHC 387 (Pat)
- Fibrogen v Akebia [2021] EWCA Civ 1279
- Sandoz Ltd and another v Bristol-Myers Squibb Holdings Ireland Unlimited Co and another [2022] EWHC 822 (Pat)

- Saint-Gobain Adfors SAS v 3M Innovative Properties Co [2022] EWHC 1018 (Pat)

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Headnote:

I. Evidence submitted by a patent applicant or proprietor to prove a technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date.

II. 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.

Europäisches Patentamt
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Große Beschwerdekammer
Enlarged Board of Appeal
Grande Chambre de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: G 0002/21

D E C I S I O N
of the Enlarged Board of Appeal
of 23 March 2023

Appellant: (Opponent)	SYNGENTA LIMITED Syngenta Jealott's Hill International Research Centre Bracknell Berkshire RG42 6EY (GB)
Representative:	HGF HGF BV Benoordenhoutseweg 46 2596 BC The Hague (NL)
Respondent: (Patent Proprietor)	Sumitomo Chemical Company, Limited 27-1, Shinkawa 2-chome, Chuo-ku Tokyo 104-8260 (JP)
Representative:	Winter, Brandl - Partnerschaft mbB Alois-Steinecker-Straße 22 85354 Freising (DE)
Referring decision:	**Interlocutory decision T 0116/18 of the Technical Board of Appeal 3.3.02 of the European Patent Office of 11 October 2021.**

Composition of the Board:

Chairman: C. Josefsson
Members: I. Beckedorf
F. Blumer
T. Bokor
P. Catallozzi
P. Gryczka
A. Ritzka

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Summary of Facts and Submissions

Referred points of law

I. By interlocutory decision T 116/18 of 11 October 2021 (hereinafter: the referring decision), Technical Board of Appeal 3.3.02 (hereinafter: the referring board) referred the following questions of law to the Enlarged Board of Appeal (hereinafter: the Enlarged Board) for decision under Article 112(1)(a) EPC in combination with Article 22 RPBA 2020:

If for acknowledgement of inventive step the patent proprietor relies on a technical effect and has submitted evidence, such as experimental data, to prove such an effect, this evidence not having been public before the filing date of the patent in suit and having been filed after that date (post-published evidence):

1. *Should an exception to the principle of free evaluation of evidence (see e.g. G 3/97, Reasons 5, and G 1/12, Reasons 31) be accepted in that post-published evidence must be disregarded on the ground that the proof of the effect rests* ***exclusively*** *on the post-published evidence?*

2. *If the answer is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have considered the effect plausible (ab initio plausibility)?*

3. *If the answer to the first question is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have seen no reason to consider the effect implausible (ab initio implausibility)?*

Patent in suit

II. European Patent No. 2 484 209 (hereinafter: the patent) concerns insecticide compositions and originates from European patent application No. 12 002 626.5, which is a divisional application of European patent application No. 05 719 327.8.

III. The patent as granted comprises two sets of claims for different contracting states, i.e. a set of claims (a) for the contracting states IS and LT and a set of claims (b) for the contracting states AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, MC, NL and SE. The respective claim 1 is directed to an insecticide composition, whereby the two claim sets differ in that claim 1(b), in addition to claim 1(a), contains a disclaimer for certain compounds. Both sets of claims also contain method claims for controlling an insect pest.

Appeal proceedings

IV. The patent had been opposed under all grounds for opposition pursuant to Article 100(a) to (c) EPC for lack of novelty and of inventive step, insufficiency of disclosure and added subject-matter.

V. The opponent appealed against the decision of the opposition division rejecting the opposition pursuant to Article 101(2) EPC.

VI. The Enlarged Board notes the following points from the referring decision:

(1) According to the referring board (points 2.1 to 2.3 of the Reasons for the referring decision), the patent (paragraphs [0002] to [0004]) acknowledges, by reference to previously published patent

documents, that both thiamethoxam and the compounds according to the claimed formula Ia were known for their insecticidal activity before the priority date of the patent. According to the patent (paragraph [0008]), the inventors have found that mixtures of thiamethoxam and compounds according to claimed formula Ia can produce an insecticidal activity which is greater than that which would have been expected based on their respective individual activities. This means that according to the patent, an insecticide composition according to claim 1 can exhibit an over-additive, i.e. synergistic, effect. To clarify whether a certain combination of insecticides acts synergistically, the patent first determines the activities of the individual insecticides, where the activity is the death rate, i.e. the percentage of dead insects, observed when a certain number of insects is exposed to a certain amount of insecticide for a certain period of time. From these individual activities, an expected activity for the joint use of both insecticides is calculated using Colby's equation. This expected activity value corresponds to a purely additive effect of both insecticides. If the actually determined activity of the combination of both insecticides is above this expected value, the insecticides act synergistically together. If it is below this value, the insecticides of the combination act antagonistically. The use of this approach to assess the presence/absence of synergism between insecticides was undisputed between the parties. The patent (paragraph [0058]) contains a list of examples of insect pests which can be controlled with the above compositions. Among the

insect pests mentioned are *Spodoptera litura*, *Plutella xylostella* and *Chilo suppressalis*.

(2) The referring board acknowledged sufficiency of disclosure of the claimed invention. It held that the question whether there was any synergy achieved was rather to be assessed under Articles 100(a) and 56 EPC (point 9 of the Reasons for the referring decision), instead of under Article 100(b) EPC.

(3) In respect of the ground for opposition pursuant to Articles 100(a) and 54 EPC, the referring board found that none of the prior art relied upon by the opponent for lack of novelty of the claimed subject-matter prejudiced the maintenance of the patent (point 10 of the Reasons for the referring decision).

(4) Concerning the ground for opposition pursuant to Articles 100(a) and 56 EPC, the referring board concluded (points 11 and 12 of the Reasons for the referring decision) that the assessment of inventive step of the claimed subject-matter of the patent hinged on whether evidence not public before the filing date of the patent and filed after that date could be taken into consideration in view of the so-called plausibility case law.

For inventive step, the patent proprietor relied on, *inter alia*, post-published evidence D21 (test data) in support of a synergistic effect. In view of the parties' different positions on the applicability of the so-called plausibility case law, both formulated opposing requests as to whether post-published evidence D21 should be taken into consideration.

The opponent also relied on post-published evidence for inventive step, namely D23 (test data), which the referring board decided to admit into the proceedings on procedural grounds (points 3 to 6 of the Reasons for the referring decision).

The referring board concluded that, if only the data in the patent and D23 were taken into account, the patent proprietor's main request would not be allowable. However, if D21 was also to be taken into account, the patent proprietor's main request would be allowable as the post-published experimental data in D21 were the only but crucial proof for the alleged synergic effect (point 12.6 of the Reasons for the referring decision).

(5) In point 13 of the Reasons for the referring decision, the referring board, while assuming that the post-published evidence D21 was not excluded from being taken into account for procedural grounds but did form part of the proceedings, discusses three diverging lines of case law from the boards of appeal regarding the circumstances under which the evidence can or cannot be taken into account on substantive grounds, depending on the credibility of the technical effect based on the evidence submitted as proof.

(6) The referring board identified a first line of case law (point 13.4 of the Reasons for the referring decision) according to which post-published evidence could be taken into account only if, given the application as filed and the common general knowledge at the filing date, the skilled person would have had reason to assume the purported technical effect to be achieved (type I, called "*ab*

initio plausibility" by the referring board). In this line of case law, for which the referring board discussed T 1329/04 (point 10 of the Reasons), T 609/02 (points 5 to 9 of the Reasons), T 488/16 (points 4.2, 4.5 and 4.19 of the Reasons), T 415/11 (points 45 to 55 of the Reasons), T 1791/11 (points 3.2.5 to 3.2.7 of the Reasons) and T 895/13 (points 15 to 17 of the Reasons), experimental data or a scientific explanation in the application as filed commonly serve as reasons which justify this assumption.

(7) The referring board discussed a second line of case law which requires that post-published evidence must always be taken into account if the purported technical effect is not implausible (type II, called "*ab initio* implausibility" by the referring board, point 13.5 of the Reasons for the referring decision). In accordance with this line of case law, post-published evidence can only be disregarded if the skilled person would have had legitimate reasons to doubt that the purported technical effect would have been achieved on the filing date of the patent. Such doubts may arise, for example, from the fact that either the application as filed or the common general knowledge on the filing date of the patent give an indication that the purported technical effect can in fact not be achieved. In this regard the referring board mentions T 919/15 (point 5.6 of the Reasons), T 578/16 (points 13 of 15 of the Reasons), T 536/07 (point 11 of the Reasons), T 1437/07 (point 38.1 of the Reasons), T 266/10 (point 37 of the Reasons), T 863/12 (point 7.3.3 of the Reasons), T 184/16 (points 2.4 to 2.7 of the Reasons) and T 2015/20 (point 2.7 of the Reasons).

(8) The referring board finally considered a third line of case law as rejecting the so-called plausibility concept altogether (type III, called by the referring board "no plausibility", point 13.6 of the Reasons for the referring decision) and discusses in this respect T 31/18 (point 2.5.2 of the Reasons) and T 2371/13 (point 6.1.2 of the Reasons).

(9) The referring board continues with further considerations of the consequences of a strict application of either the type I or the type III case law (point 13.7.1 of the Reasons for the referring decision) and on the limitations of the type I and type II case law in cases where an effect needs to be established vis-à-vis a prior-art document that has not been, and perhaps could not have been, considered by the patent applicant or proprietor (point 13.7.2 of the Reasons for the referring decision). Finally the referring board discusses an additional tension between these two types of case law on the one hand and the principle of free evaluation of evidence on the other hand (points 13.7.3 and 13.7.4 of the Reasons for the referring decision).

(10) As to the referred questions, the referring board (point 14 of the Reasons for the referring decision) notes that an answer from the Enlarged Board is needed both to ensure uniform application of the law and because points of law of fundamental importance have arisen. The three questions referred to the Enlarged Board for decision relate to the three lines of case law discussed above. The outcome of the referral is decisive for the case at issue since whether post-published evidence D21 can be taken

into account depends on this outcome, and since, furthermore, as has been set out above, if taken into account, D21 is relevant to a final decision on inventive step.

Course of the proceedings before the Enlarged Board

VII. The parties to the appeal proceedings are parties to the present proceedings under Article 112(2) EPC. The Enlarged Board invited both the patent proprietor and the opponent to comment in writing on the questions of law referred to the Enlarged Board.

VIII. Pursuant to Article 9, first sentence, RPEBA, the Enlarged Board also invited the President of the European Patent Office (hereinafter: President of the EPO) to comment in writing on the questions of law. He submitted his comments on 22 April 2022. The patent proprietor and the opponent were given the opportunity to submit their observations on those comments in compliance with Article 9, second sentence, RPEBA. The opponent responded with a letter dated 30 September 2022.

IX. Observations were filed by the opponent on 29 April 2022.

X. By communication published in the Official Journal of the EPO (OJ EPO 2021, A102), the Enlarged Board gave third parties the opportunity to file written statements in accordance with Article 10 RPEBA and received 20 *amicus curiae* briefs and one third party observation:

(1) F. Carlsson, 10 December 2021;
(2) H.-R. Jaenichen, 11 January 2022;
(3) R. Kiebooms, 12 January 2022 (filed as third party observation);
(4) Beiersdorf AG, 2 March 2022;
(5) E. Wunder, 17 March 2022;
(6) P.H. van Deursen, 22 March 2022;

(7) International Federation of Intellectual Property Attorneys (FICPI), 19 April 2022;
(8) BAYER AG, 20 April 2022;
(9) Institute of Professional Representatives before the EPO (epi), 22 April 2022;
(10) European Patent Litigators Association (EPLIT), 26 April 2022;
(11) P. de Lange, 28 April 2022;
(12) International Association for the Protection of Intellectual Property (AIPPI), 28 April 2022;
(13) Medicines for Europe, 29 April 2022;
(14) Patentanwaltskammer, 29 April 2022;
(15) UK BioIndustry Association (BiA), 29 April 2022;
(16) Fresenius Kabi Deutschland GmbH, 29 April 2022;
(17) Compagnie Nationale des Conseils en Propriété Industrielle (CNCPI), 29 April 2022 ;
(18) European Federation of Pharmaceutical Industries and Associations (efpia), 29 April 2022;
(19) BASF SE, 29 April 2022;
(20) IP Federation, 29 April 2022;
(21) Chartered Institute of Patent Attorneys (CIPA), 29 April 2022.

XI. In preparation for the oral proceedings, the Enlarged Board issued a communication pursuant to Articles 13 and 14(2) RPEBA on 13 October 2022. That communication was intended to draw the parties' attention to certain potentially significant legal issues with regard to the referred questions and to afford them an opportunity to comment on these.

XII. The patent proprietor and the opponent responded to the Enlarged Board's communication with letters dated 10 November 2022 and 8 November 2022, respectively. Additional third party observations were received from Medicines for Europe, Fresenius Kabi Deutschland GmbH and in anonymous form.

XIII. Oral proceedings were held before the Enlarged Board on 24 November 2022 in the presence of the patent proprietor and the opponent, as well as the President of the EPO.

XIV. At the end of the oral proceedings, the Chairman announced that the Enlarged Board would issue the decision in writing in due course.

Summary of the essential arguments presented in the proceedings

Admissibility of the referral

XV. The patent proprietor, the opponent, the President of the EPO and the majority of third parties either explicitly or implicitly considered the referral admissible.

BAYER AG and epi submitted that the referral should be regarded as inadmissible because the outcome of the appeal case was not dependent on the referred questions. According to BAYER AG, the answers should not impact the outcome either way when considering the principle of equal treatment of the parties. Post-published evidence may be taken into account based on the principle of free evaluation of evidence, or it may not. Hence, if the opponent was allowed to file verifiable facts to substantiate doubts, the patent proprietor must be allowed to likewise file verifiable facts to substantiate the effect made plausible in the application. Either way, in the case before the referring board this would mean that the subject-matter of the claims was to be considered inventive. For epi, document D21 needed to be taken into account by the referring board under the type I approach and pointed out that there was no divergence in the case law.

General aspects

XVI. The patent proprietor derived from the case law of the boards of appeal in general and from the discussion in the context of the particular case leading to the referring decision that there were two different standards.

The first standard was for acknowledging a technical effect, i.e. whether the purported technical effect was achieved over the whole range of the claim. For this, the patent proprietor referred to decision T 939/92 (point 2.6 of the Reasons), which required that in order for a technical effect to be taken into account, it must be credible that substantially all claimed embodiments possessed the technical effect. If that requirement was fulfilled, the technical effect was to be taken into consideration for determination of an objective technical problem.

The second standard was for allowing a post-published document supporting a technical effect to be taken into account. For this the patent proprietor referred to decision T 1329/04 (point 11 of the Reasons) according to which such a document could only be taken into account when it was at least plausible that a solution had been found to the problem which was purportedly solved. Once this standard was met, the applicant or patent proprietor could rely on a post-published document to demonstrate that the technical effect had been achieved over the whole range of the claim.

XVII. The opponent submitted that referred question 1 addressed both substantive patent law and procedural law issues, i.e. the issue whether an alleged technical effect, for which no direct proof existed in the application as

filed, could be relied upon, and the issue whether post-published evidence should be disregarded as an exception to the principle of free evaluation of evidence. These two aspects should be clearly distinguished from each other.

XVIII. The President of the EPO considered that the referred questions required clarification as to their scope and advocated that the questions be re-ordered and that either the questions be re-phrased or that their scope be extended to cover the concept of plausibility also under the patentability requirement of sufficiency of disclosure under Article 83 EPC. Efpia, likewise, suggested that the questions be clarified but to a lesser extent than the President of the EPO.

Equally, epi, Medicines for Europe, Fresenius Kabi Deutschland GmbH and BASF SE suggested to re-formulate question 1. P. de Lange advocated a complete re-formulation of the referred questions to focus on whether an additional requirement for "technical support in the application as filed" was to be applied.

The opponent, in its response to the Enlarged Board's communication pursuant to Articles 13 and 14(2) RPEBA, asked the Enlarged Board for guidance as to how far principles governing post-published evidence in the context of assessing inventive step could also be applied in the context of assessing sufficiency of disclosure.

XIX. Some third parties (FICPI, epi, Patentanwaltskammer) encouraged that referred questions 2 and 3 be answered irrespective of the answer given to question 1.

XX. The opponent, the President of the EPO and a number of third parties (H.-R. Jaenichen, FICPI, BAYER AG, epi, AIPPI, efpia, IP Federation, CIPA) each presented the

position that "plausibility" *per se* was not a patentability requirement but was linked to the question whether or not an invention could be acknowledged and whether an applicant or patent proprietor was actually in possession of an invention at the time of filing the patent application.

XXI. In another *amicus curiae* brief (BiA), instead of suggesting any specific answer to the referred questions, the Enlarged Board was requested to consider an approach which lay between the two extremes of excluding post-filed data completely and not taking "plausibility" into account at all in deciding whether to admit such post-filed data. Also BASF SE refrained from proposing specific answers and submitted more on the substance that technical effects to be relied on for justification of patentability must be credibly disclosed in the original application documents to the skilled person's satisfaction, whereby the detail of factual substantiation required for a credible disclosure was to be determined on a case by case basis.

Negative answer to question 1

XXII. Arguments generally in favour of applying the principle of free evaluation of evidence in an unqualified manner also in respect of post-published evidence on which a technical effect exclusively rests were submitted by the President of the EPO and were supported by various third parties (F. Carlsson, Beiersdorf AG, E. Wunder, FICPI, BAYER AG, epi, EPLIT, Patentanwaltskammer, CNCPI, efpia, CIPA).

According to the President of the EPO, post-published evidence to prove a technical effect for acknowledgement

of inventive step could not be relied on to fully replace such an indication in the application as filed. However, this does not require an exception to the principle of free evaluation of evidence. For this reason, the President of the EPO proposed to answer question 1 in the negative but, irrespective of this, submitted arguments understood to be generally in favour of the approach referred to in question 2.

Epi, supported by CIPA, additionally argued that any inquiry as to the credibility of a technical effect at the filing date of the application was entirely separate and could logically only ensue after the free and full evaluation of the post-published evidence had established that the technical effect did occur. However, insofar as the technical effect proven for the first time by the post-published evidence had not been mentioned in the application as filed, the applicant or patent proprietor could only rely on the technical effect in the examination of inventive step if that effect was within the spirit of the invention disclosed in the application as filed.

More generally, CNCPI considered the introduction of an exception to the principle of free evaluation of evidence unjustified, because the question of the proof of the technical effect in the context of the assessment of the inventive step was a jurisprudential construction.

According to some other third parties (Beiersdorf AG, BAYER AG, epi, EPLIT, CIPA) an affirmative answer to question 1 was incompatible with the notion of Article 117(1) EPC which allowed for a number of means of giving or obtaining evidence which were by their very nature post-published, i.e. hearing of parties, requests for information, hearing witnesses, opinions by experts

and inspection. In another *amicus curiae* brief (Patentanwaltskammer), Article 113(1) EPC was referred to as being contradicted by a firm ruling for considering post-published technical information. Rather, post-published evidence had to be freely evaluated for its probative value. Any effect made plausible in the original application documents could be challenged or defended by evidence created or made after the priority date of the patent application.

A further third party (E. Wunder) argued that, like the assessment of the closest prior art, the technical effect had to be assessed at the time a decision was taken.

Affirmative answer to question 1

XXIII. Arguments generally in favour of accepting an exception to the principle of free evaluation of evidence by disregarding post-published evidence on which a technical effect exclusively rests were originally submitted by the opponent and also supported by various third parties (P.H. van Deursen, P. de Lange, Medicines for Europe, Fresenius Kabi Deutschland GmbH, IP Federation, and an anonymous third party observation).

The opponent, supported by Medicines for Europe and Fresenius Kabi Deutschland GmbH, originally considered it inequitable if a technical contribution to the art could be a mere allegation to justify a monopoly right stemming from a granted patent based exclusively on evidence submitted years after the filing date. Doing so would allow a very low threshold to be met by an applicant at the time of filing a patent application because it would allow for a technical effect to be a mere speculation that could not technically contribute to the art. Thus,

disregarding post-published evidence as the only piece of evidence for an alleged technical effect, for which no proof existed in the application as originally filed and which was not plausible on the filing date of the patent application, did not infringe the principle of free evaluation of evidence.

However, in their response to the Enlarged Board's communication pursuant to Articles 13(2) and 14 RPEBA (point 12 thereof), the opponent agreed with the Enlarged Board's view that the principle of free evaluation of evidence does not appear to allow the disregarding of evidence *per se* insofar as it is submitted and relied upon by a party in support of an inference which is challenged and is decisive for the final decision.

Some third parties (P.-H. van Deursen, P. de Lange, Medicines for Europe) pursued a more advanced approach of excluding from consideration any post-published evidence filed to support for a claimed technical effect when assessing inventive step. The principle of legal certainty of third parties required that the evidence underpinning the claim was known at the filing date and should be unalterable during the claim's lifetime.

Affirmative answer to question 2

XXIV. Arguments generally in favour of taking into consideration post-published evidence if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have considered the effect credible were submitted by the opponent and were supported by various third parties (Medicines for Europe, IP Federation). Some third

parties, although suggesting that question 1 be answered in the negative, supported an affirmative answer to question 2, either as additional considerations (FICPI, epi) or in the event that question 1 was answered in the affirmative (BAYER AG, CIPA). Despite the fact that the President of the EPO did not directly propose to answer question 2 in the affirmative, his arguments are understood to be generally in favour of this approach.

According to the opponent and some third parties (Medicines for Europe, IP Federation) it was essentially a matter of substantive patent law that a patent could only be granted if there was a patentable invention as of the filing date of a patent application. Thus, an alleged technical effect was required to be more than a mere speculation, but must be derivable from the application as originally filed and as constituting a technical contribution to the prior art. To this end, post-published evidence in support of an alleged technical effect present as of the filing date could be taken into consideration.

The opponent, in the response to the Enlarged Board's communication pursuant to Articles 13 and 14(2) RPEBA suggested the following test:

(i) A purported technical effect is credible, if a skilled person familiar with the art, having regard to the application as filed, is satisfied that the purported technical effect will occur.
(ii) The skilled person must also be satisfied that the purported technical effect will occur over the ambit of the claim.
(iii) If these conditions are not fulfilled, the post-published evidence should not be further considered for the assessment of inventiveness.

The President of the EPO emphasised that there was no distinct, separate patentability requirement of "plausibility" but that it was to be understood from the EPC that an invention to be patentable required that a technical effect was attainable. An alleged technical effect as an inherent feature of any invention complying with Articles 56 and 83 EPC had to be made on the basis of the content of the application as filed in combination with the common general knowledge. A lack of such disclosure could not be made up for at a later stage by submitting post-published evidence showing that the alleged technical effect was indeed achieved. Post-published evidence could be taken into account to corroborate a credible disclosure at the filing date or to refute any allegation from opponents that the claimed technical effect could not be achieved. The evidence submitted by a patent proprietor to prove an alleged technical effect, which was already credibly disclosed at the filing date, or submitted by the opponent to prove that this technical effect could not be achieved, had to be assessed in accordance with the principle of free evaluation of evidence.

FICPI argued that in special circumstances, when the attainment of a particular technical effect was treated in a claim and thus part of the subject-matter of the invention, it was appropriate to consider whether the claimed effect was rendered credible in the application as filed. However, a claimed technical effect could be rendered credible even without having been proven, e.g. by means of extrapolation, analogy or a theoretical rationale, and the principle of free evaluation of evidence should be preserved in order to allow later proof, if needed, of a claimed effect that was rendered credible in the application.

BAYER AG and CNCPI also argued that the applicability of any approach had to be done on a case-by-case basis and depended on different aspects, like the respective technical field, the prior art and the predictability of the claimed technical effect without these aspects *per se* contradicting one another.

Arguments against the approach underlying referred question 2

XXV. The patent proprietor submitted that the approach underlying referred question 2 was at most applicable for the assessment of sufficiency of disclosure (Article 83 EPC) for which it had initially been introduced by decision T 609/02, in particular where the technical effect was stated in the claim (T 939/92, point 2.2.2 of the Reasons). It should, however, not be applied to the assessment of inventive step (Article 56 EPC) of a claimed subject-matter because it would be extremely disproportional in terms of the legal effect, the awareness of the patent applicant and the burden of proof.

Affirmative answer to question 3

XXVI. The patent proprietor argued in favour of taking into consideration post-published evidence as a proof of an asserted technical effect if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have seen no reason to consider the effect non-credible, this in particular with regard to patents directed to medical use. In such cases the applicant would be aware of the importance of the

technical effect from the beginning of the patent granting procedure and would have mentioned it already in the patent application. Thus, the threshold for sufficiency of disclosure should normally be addressed by the applicant. With regard to inventive step, however, it would be highly unpredictable which technical effect the patent applicant should rely upon as the discussion of the technical effect depended on the choice of the closest prior art that is usually introduced after the filing date. Hence, the applicant would often be forced to argue for a technical effect of a distinguishing feature not focussed on when filing the application.

One third party (IP Federation) suggested to answer all three referred questions in the affirmative. It should be permissible to take into account post-filed data if, based on the information in the patent application in suit and/or the common general knowledge, the skilled person at the filing date of the application would have seen no reason to consider the technical effect non-credible, including if they considered the technical effect to be credible, based on the information in the patent application and/or the common general knowledge.

Other third parties, although suggesting that question 1 be answered in the negative, supported an affirmative answer to question 3, either as additional considerations (FICPI) or in the event that question 1 was answered in the affirmative (BAYER AG, epi, CIPA) in order to preserve the ability of an applicant to adduce additional evidence to support the technical effect associated with the subject-matter of the invention that, although not explicitly disclosed in the application as filed, sustained the spirit and character of the disclosed invention and was not implausible. CIPA advocated that

any requirement for information in respect of "plausibility", or lack of "implausibility", at the filing date should be minimal. For example, it should suffice if the technical effect ultimately relied upon was merely "not completely implausible", especially bearing in mind that at the filing date the applicant may not know the closest prior art from which the claimed invention must be distinguished.

Arguments against the approach underlying referred question 3

XXVII. The opponent argued that the approach underlying referred question 3 lowered the threshold to patentability significantly and allowed for patents to be granted on the basis of a at the filing date merely speculative technical effect, as opposed to a genuine technical contribution. If it was allowed to define an invention after the filing date, then anything disclosed in the application as filed could be "transformed" into an invention after that effective date. Such an approach was incompatible with the requirement of Article 52(1) EPC according to which a patent shall be granted for any invention, provided that the invention had already been made before the patent application was filed.

Fresenius Kabi Deutschland GmbH additionally argued that although the burden of proof for a claimed technical effect normally rested with the patent applicant or proprietor, and the hurdle for opponents and examiners implied by question 3 was close to unsurmountable, it placed them at a severe disadvantage, and was simply unfair.

Reasons

Scope and Focus of the referral

1 The points of law referred to the Enlarged Board in the present case address two issues, namely whether the principle of free evaluation of evidence requires a qualification in respect of certain evidence relied upon for a purported technical effect in the assessment of inventive step, and the relevant criteria to be applied with regard to such a technical effect.

2 The referring board addressed said points in three questions whereby questions 2 and 3 should become relevant only if, in affirming question 1, an exception to the general principle of free evaluation of evidence was to be acknowledged.

3 The President of the EPO and some third parties suggested a re-ordering and re-phrasing of the referred questions to the effect that questions 2 and 3 be answered first, before discussing the qualified and unqualified applicability of the principle of free evaluation of evidence.

4 The Enlarged Board is not bound by the way a board of appeal formulates questions of law and may re-draft such questions. However, the specific formulation chosen by a referring board is the starting point to define what a referring board considers a point of law requiring a decision by the Enlarged Board under Article 112(1)(a) EPC. The Enlarged Board may deviate from the wording if this is required to better reflect the true object and focus of the referral (see examples in G 2/08, points 1 and 3 of the Reasons; G 2/10, point 1 of the Reasons; G 1/12, point 16 of the Reasons; G 1/13, point 1 of the Reasons; G 3/14, Section B of the

Reasons; G 1/19, Section A of the Reasons; G 3/19, Section III. of the Reasons; G 1/21, point 20 of the Reasons).

5 The Enlarged Board notes from the specific and unambiguous drafting of the referred questions that there is no doubt that the referring board reflected on the hierarchy and dependency of the referred questions and that it is minded to take a final decision on the appeal case already in the event that the Enlarged Board answers question 1 in the negative, without answering questions 2 and 3.

6 This also appears to be in line with the submission in two *amicus curiae* briefs that any inquiry as to the purported technical effect is entirely separate and could logically only ensue after a free and full evaluation also of any relevant post-published evidence.

7 Thus, the Enlarged Board does not see a need or a justification for re-ordering or re-phrasing the referred questions. While the Enlarged Board is by no means required to add considerations on aspects relevant in the context of the referral as raised in the other two referred questions, it is aware of the suggestion made by the President of the EPO and various third parties to examine what they consider to be the primary aspect of the referral, i.e. the relevant principles to be applied with regard to examination of such a purported technical effect for inventive step.

8 The President of the EPO additionally proposes to extend the scope of the referred questions beyond the issues for assessing inventive step to the assessment of sufficiency of disclosure pursuant to Article 83 EPC.

9 The Enlarged Board acknowledges that it is primarily for the referring board to decide what point of law it considers of such importance that it cannot decide on the appeal before it without first having received an answer to that question by

the Enlarged Board. Such a point of law can only be of decisive importance in the specific context in which it arises to avoid a referral of points of law of a mere academic nature.

10 The Enlarged Board notes that the referring board clearly described the factual and legal context within which the point of law arises, i.e. the assessment of inventive step of the claimed subject-matter in the legal framework of Article 56 EPC. The referring board explicitly found that the ground for opposition pursuant to Article 100(b) EPC was not relevant for deciding on the appeal, as already held by the opposition division in the decision under appeal. The referring board evidently considered sufficiency of disclosure of the claimed invention not to be a decisive issue so that for the referring board the referred questions of law have no bearing on whether or not, and to which extent, an exception to the principle of free evaluation of evidence shall be made in the legal framework of Article 83 EPC.

11 Therefore, the scope of the point of law defined by the referred questions and the reasons for the referring decision does not allow for or require that the referred questions be re-phrased by adding a reference to the issue of sufficiency of disclosure and Article 83 EPC.

12 However and notwithstanding said clear focus of the referred questions on inventive step, the Enlarged Board is aware of the respective case law on sufficiency of disclosure.

Admissibility of the referral

13 Pursuant to Article 112(1)(a) EPC, a board of appeal shall, during proceedings on a case, either of its own motion or

following a request from a party to the appeal, refer any question to the Enlarged Board if it considers that a decision is required in order to ensure uniform application of the law, or if a point of law of fundamental importance arises.

14 In its reasoning, the referring board sets out in detail why an answer to the referred questions is indispensable for its decision on the appeal before it, since, in its view, the final decision on the appeal hinges on whether post-published evidence submitted by the patent proprietor to prove a technical effect can be taken into account or must be disregarded. So, an answer to at least some of the referred questions is required to enable the referring board to come to a final decision on the appeal before it.

15 The Enlarged Board is also convinced that the referred questions raise a point of law of fundamental importance, since the answers will have an impact beyond the specific case at hand and will be relevant to a large number of similar cases before the boards of appeal and before the examining and opposition divisions. Thus, a decision of the Enlarged Board on the referred questions will serve to bring about a uniform application of the law (see G 1/12, points 11 and 12 of the Reasons).

16 Some third parties argued that the referral should be regarded inadmissible, because the claimed invention should be considered inventive when taking into account the evidence submitted by both the opponent and the patent proprietor in support of their respective allegations as to whether or not the claimed invention produced the technical effect relied upon by the patent proprietor and disputed by the opponent. It was likewise to be considered inventive when disregarding the respective evidence submitted by both parties.

17 The Enlarged Board notes that the referring board took a discretionary decision to admit the post-published evidence filed by the opponent (test data D23), but that it considered itself to not be in a position to also admit the post-published evidence filed by the patent proprietor (test data D21) without having first received an answer by the Enlarged Board on a point of law which the referring board judged decisive. As the referring board's procedural decision is not subject to a review by the Enlarged Board in the course of proceedings under Article 112(1)(a) EPC, it does not prejudice the admissibility of the referral with regard to precisely this second issue of whether it may or may not admit the patent proprietor's test data.

18 One third party questioned the referring board's assumption of divergency of the case law and argued that, by its perception, the boards of appeal applied the case law consistently and on the basis of their technical evaluation of the facts of the case in question.

19 However, the Enlarged Board accepts the referring board's perception of divergencies in the case law, if only for the use of different conceptual and terminological approaches underlying questions 2 and 3. This is confirmed by the submissions of the opponent, the comments of the President of the EPO, and in several *amicus curiae* briefs. Confronted with these approaches, the referring board considered itself unable to arrive at a clear conclusion for the case at hand.

20 Consequently, the referral is admissible.

Preliminary considerations

21 The referring decision points out in the introductory part of the referred questions that three questions of law arise in

the context of examining inventive step of a claimed subject-matter.

22 In accordance with Article 52(1) EPC, patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

23 According to the established jurisprudence of the boards of appeal, the assessment of inventive step is to be made at the effective date of the patent on the basis of the information in the patent together with the common general knowledge then available to the skilled person (see T 609/02, T 1329/04, T 1545/08; see also Case Law of the Boards of Appeal [hereinafter: CLB], 10th edition, 2022, I.D.4.3.3, and the decisions therein).

24 The boards of appeal and the administrative departments of the EPO regularly apply the "problem and solution approach" in the course of deciding whether or not a claimed subject-matter involves an inventive step and fulfils the requirements of Article 56 EPC. This approach consists essentially of the following methodologic steps (see CLB, 10th edition, I.D.2, and the decisions therein):

(a) identifying the "closest prior art";
(b) comparing the subject-matter of the claim at issue with the disclosure of the closest prior art and identifying the difference(s) between both;
(c) determining the technical effect(s) or result(s) achieved by and linked to these difference(s);
(d) defining the technical problem to be solved as the object of the invention to achieve these effect(s) or result(s); and
(e) examining whether or not a skilled person, having regard to the state of the art within the meaning of Article 54(2) EPC, would have suggested the claimed technical features in

order to obtain the results achieved by the claimed invention.

25 The technical problem must be derived from effects directly and causally related to the technical features of the claimed invention. An effect could not be validly used in the formulation of the technical problem if the effect required additional information not at the disposal of the skilled person even after taking into account the content of the application in question (see CLB, 10th edition, I.D.4.1, and the decisions therein).

26 Step (c), which is the most relevant in the context of the present referral, requires that, in order to determine the objective technical problem, the technical results and effects achieved by the claimed invention as compared with the closest prior art must be assessed. According to the established case law of the boards of appeal (see CLB, 10th edition, I.D.4.2, and the decisions therein) it rests with the patent applicant or proprietor to properly demonstrate that the purported advantages of the claimed invention have successfully been achieved.

Principle of free evaluation of evidence

27 The first referred question concerns the point of law whether a board of appeal is required to deviate from the principle of free evaluation of evidence in respect of post-published evidence submitted as the exclusive support of a purported technical effect when assessing inventive step.

28 The structure of the three referred questions and their interdependency with each other suggest a specific understanding of the principle of free evaluation of evidence by the referring board. The reasoning in point 13.7.3 of the

Reasons of the referring decision appears to presume that the principle of free evaluation of evidence does not directly allow for, but conflicts with what the referring board describes as standards for the reliance on certain evidence for a purported technical effect. The referring board, though without discussing this further, raises the point that it is "not immediately clear what could be the legal basis for preventing the patent proprietor from relying on a particular type of evidence of a fact relevant to the outcome of the proceedings. Likewise, it is not clear on what basis a board would be prohibited from taking into account evidence it finds convincing and decisive."

29 Neither the EPC nor the case law of the boards of appeal lay down formal rules for the evaluation of evidence. In G 1/12 (point 31 of the Reasons), referring to G 3/97 (point 5 of the Reasons) and to G 4/97 (point 5 of the Reasons), the Enlarged Board recalled that proceedings before the EPO are conducted in accordance with the principle of free evaluation of evidence.

30 Said principle can be defined in abstract and general terms as allowing and, by the same token, requiring a judicial body, like the boards of appeal, to decide according to its own discretion and its own conviction, by taking account of the entire content of the parties' submissions and, where appropriate, any evidence admissibly submitted or taken, without observing formal rules, whether a contested factual assertion is to be regarded as true or false.

31 It does not mean that this evaluation of evidence may be arbitrary, rather the evidence must be assessed comprehensively and dutifully. The only decisive factor is whether the judge is personally convinced of the truth of the factual allegation, i.e. how credible the judge classifies a piece of evidence. To do this, the judge must put all the

arguments for and against a factual statement in relation to the required standard of proof. In doing so, the judge remains bound by the laws of the logic and by probability based on experience. The reasons that led the judge to be convinced of the correctness or incorrectness of a contested allegation as to fact are to be set out in the decision.

32 The principle of free evaluation of evidence may not be used to disregard evidence *per se* insofar as it is admissibly submitted and relied upon by a party in support of an inference which is challenged and is decisive for the final decision. Disregarding it as a matter of principle would deprive the party submitting and relying on such evidence of a basic legal procedural right generally recognised in the EPC Contracting States and enshrined in Articles 113(1) and 117(1) EPC (see also T 1110/03, point 2 of the Reasons, T 1797/09, point 2.9 of the Reasons, T 419/12, point 2.1.3 of the Reasons, and T 2294/12, point 1.1.3 of the Reasons).

33 This definition, which applies likewise to decisions taken by the administrative departments of the EPO in patent granting procedures, is in conformity with the established jurisprudence of the boards of appeal (see CLB, 10th edition, III.G.4.1, and the decisions therein) and finds support in patent law commentaries (see Unland in: Benkard, EPÜ, Art. 117, no. 39; Bühler in Singer/Stauder/Luginbühl, EPÜ, Art. 117, no. 23; Schulte, Patentgesetz, introduction, no. 155; Visser's Annotated European Patent Convention, Art. 117, point 2, last paragraph, all with further references).

34 The deciding bodies under the EPC have the power and the duty to assess whether the alleged facts are sufficiently established on a case-by-case basis. Under the principle of free evaluation of evidence, the respective body takes its decision on the basis of all the relevant evidence available in the proceedings, and in the light of its conviction

arrived at freely when evaluating whether an alleged fact is or is not to be regarded true and proven. Free evaluation of admissibly filed evidence relevant for deciding the case at hand means that there are no firm rules according to which certain types of evidence are, or are not, convincing.

Existing jurisprudence of the Enlarged Board of Appeal

35 There is no decision or opinion of the Enlarged Board dealing directly with the principle of free evaluation of evidence in support of an alleged technical effect. The Enlarged Board has addressed the principle of free evaluation of evidence only in different contexts, i.e. the admissibility of an opposition to a European patent filed on behalf of a third party (consolidated G 3/97 and G 4/97) and the admissibility of an appeal filed by a person appearing at first sight not to have standing to do so (G 1/12).

36 In consolidated decisions G 3/97 and G 4/97 the Enlarged Board held (points 1(a), 1(b) and 2 of the Order of decision G 3/97, and points 3(a), 3(b) and 4 of the Order of decision G 4/97, emphasis added):

"An opposition is not inadmissible purely because the person named as opponent according to Rule 55(a) EPC is acting on behalf of a third party.
Such an opposition is, however, inadmissible if the involvement of the opponent is to be regarded as circumventing the law by abuse of process.
In determining whether the law has been circumvented by abuse of process, the principle of the free evaluation of evidence is to be applied. The burden of proof is to be borne by the person alleging that the opposition is inadmissible. The deciding body has to be satisfied on the basis of clear and convincing evidence that the law has been circumvented by abuse of process."

37 In G 1/12 the Enlarged Board held (Order with added emphasis):

"The answer to reformulated question (1) - namely whether when a notice of appeal, in compliance with Rule 99(1)(a)

EPC, contains the name and the address of the appellant as provided in Rule 41(2)(c) EPC and it is alleged that the identification is wrong due to an error, the true intention having been to file on behalf of the legal person which should have filed the appeal, is it possible to correct this error under Rule 101(2) EPC by a request for substitution by the name of the true appellant - is yes, provided the requirements of Rule 101(1) EPC have been met.
Proceedings before the EPO are conducted in accordance with the principle of free evaluation of evidence. This also applies to the problems under consideration in the present referral.
In cases of an error in the appellant's name, the general procedure for correcting errors under Rule 139, first sentence, EPC is available under the conditions established by the case law of the boards of appeal."

Evaluation of evidence before the boards of appeal

38 Article 117 EPC provides for the submission of evidence in the administrative proceedings before the receiving section, the examining and opposition divisions and the legal division as well as in the judicial proceedings before the boards of appeal (see CLB, 10th edition, III.G.1).

39 The boards of appeal have addressed multiple issues of admissibility and taking of evidence in their case law. In addition, they have elaborated specific principles governing the evaluation of evidence, the standard of proof and the allocation of the burden of proof in order to ensure that EPO proceedings are conducted in a fair and consistent manner (see CLB, III.G.1, 10th edition, and the decisions therein).

40 In accordance with the principle of free evaluation of evidence, any kind of evidence, regardless of its nature, is admissible (see T 482/89 and T 558/95). Parties can freely choose the evidence they wish to submit, whereby the kinds of evidence listed in Article 117(1) EPC are merely examples (see T 543/95 and T 142/97).

41 Articles 113(1) and 117(1) EPC embody a basic procedural right generally recognised in the EPC contracting states, i.e. the right to give evidence in appropriate form and the right to have that evidence heard (see T 1110/03). A decision should discuss the facts, evidence and arguments which are essential to the decision in detail (see e.g. T 278/00, see also CLB, 10th edition, III.K.3.4.4 b), and the decisions therein).

42 Whether a fact can be regarded as proven has to be assessed by the competent deciding body hearing the case having taken all the relevant evidence into consideration (T 474/04 and T 545/08 citing G 3/97, point 5 of the Reasons). All the means of giving or obtaining evidence covered by Article 117(1) EPC are subject to the discretion of that body, which will order it to be taken only if it considers this necessary (T 798/93). If the evidence offered as proof of contested facts essential to the settlement of the dispute is decisive, the body hearing the case must, as a rule, order that it be taken into account (see T 474/04). All appropriate offers of evidence made by the parties should be taken up (see T 329/02).

43 If, however, post-published evidence is considered to lack *prima facie* relevance or is not required for the decision on the issue in question of the case at hand, there is no need for it to be taken into account by the competent board of appeal (e.g. T 122/18 and T 1343/19 evidence not *prima facie* relevant; T 517/16, T 2923/18, T 2029/19, T 2963/19, T 3109/19: evidence not required or relevant; and T 2730/16: alleged technical effect no longer contested).

44 The principle of unfettered consideration and evaluation of the evidence does not apply until after an offer of evidence has been taken up and cannot be used to justify not taking evidence offered into account (see T 1363/14, T 2238/15).

45 To fulfil its power to assess whether the alleged facts are sufficiently established on a case-by-case basis, the competent deciding body takes its decision on the basis of all the evidence available in the proceedings, and in the light of its conviction arrived at freely on the evaluation of whether an alleged fact has occurred or not (see e.g. T 482/89, T 838/92, T 592/98, T 972/02, and further examples and references in CLB, 10th edition, III.G.4.1).

46 Even though different concepts as to the standard of proof have been developed in the case law of the boards of appeal, they all have in common that a judgement is to be made on the basis of the application of the principle of free evaluation of evidence (see CLB, 10th edition, III.G.4.3, and the decisions therein).

Principle of free evaluation of evidence in the Contracting States

47 Article 117(1) EPC provides for the means of giving or obtaining evidence, and Article 117(2) EPC in connection with Rules 4, 117 to 124, and 150 EPC regulate the procedure for taking such evidence. However, there are no explicit procedural provisions in the EPC on the evaluation of evidence.

48 Hence, principles of procedural law generally recognised in the Contracting States of the EPC are to be taken into account in accordance with Article 125 EPC.

49 It appears that the principle of free evaluation of evidence is known and applied in a number of Contracting States with a civil law system.

Switzerland

50 The principle of free evaluation of evidence is also acknowledged in Switzerland. The Swiss Code of Civil Procedure (Zivilprozessordnung) stipulates in Article 157 that the court forms its conviction after free evaluation of the evidence ("Das Gericht bildet sich seine Überzeugung nach freier Würdigung der Beweise.") which was interpreted by the Swiss Federal Supreme Court as a ban on fixed rules of evidence (see decision 5A_250/2012 of 18 May 2012, point E. 7.4.1 with further references). In its decisions, the Swiss Federal Patent Court refers to said provision (see Article 27 Patent Court Act (Bundesgesetz über das Bundespatentgericht - Patentgerichtsgesetz).

Germany

51 For Germany, the principle of free evaluation of evidence is provided for both in the Patent Act (§ 93(1) Patentgesetz) and in the Code of Civil Procedure (§ 286 Zivilprozessordnung). According to the former, the judge shall decide according to its independent conviction gained as an overall result of the proceedings ("Das Patentgericht entscheidet nach seiner freien, aus dem Gesamtergebnis des Verfahrens gewonnenen Überzeugung.").

France

52 French proceedings are in principle also governed by the principle of a free evaluation by the judge of the evidence submitted by the parties ("appréciation souveraine par le juge des éléments de preuve qui lui sont soumis"; see J. Passa, Traité de droit de la propriété intellectuelle, Tome 2, Brevets d'invention, protections voisines, 2013,

point 151, pages 202 and 203; J. Schmidt-Szalewski, Fasc. 4260 of Jurisclasseur Brevets, paragraph 48 "appréciation de la preuve des antériorités"). Regarding novelty however, the date, the content and the accessibility to the public of a document allegedly disclosing the invention must be certain.

The Netherlands

53 In the Netherlands, Article 152(2) of the Dutch Code of Civil Procedure (Wetboek van Burgerlijke Rechtsvordering) regulates a free evaluation of evidence, unless the law provides otherwise ("De waardering van het bewijs is aan het oordeel van de rechter overgelaten, tenzij de wet anders bepaalt."). This exception concerns rules about the conclusive evidential value of evidence. The court is obliged to accept as true certain forms of evidence; however such evidence is also subject to a rebuttal supported by evidence. Although the Dutch legal system does not provide methodological guidance for judges on the free assessment of evidence the definition by C.H. van Rhee appears to be an accepted common definition of the principle of the free assessment of evidence in Dutch civil procedural law, according to which the judge decides on proof according to his "intimate conviction", but within the boundaries set by the parties in their statements of facts.

United Kingdom (England and Wales)

54 In the United Kingdom with its common law system, there is no general principle of free evaluation of evidence. Evidence in relation to inventive step (obviousness) is considered a "jury-type question" to be decided on the facts of the particular case at hand (see Terrel on the Law of Patents by C. Birss et al, 19th edition, 2020, pages 390-400 at [12-177]-[12-212], with many examples and references). Two types

of evidence were defined and distinguished by the Court of Appeal in Mölnlycke v Procter & Gamble [1994] R.P.C. 49 at [112]: primary evidence (expert evidence) and secondary evidence (all other evidence), whereby in relation to obviousness for which an objective test is applied the primary evidence seems to be most relevant, although secondary evidence may also be treated "decisive in a proper case" (Accord v Medac [2016] EWHC 24 (Pat) at [116]; see also Schlumberger v EGMS [2010] EWCA Civ 819 at [84]-[85]; Hospira UK Ltd, v Cubist Pharmaceuticals Ltd [2016] EWHC 1285 (Pat); Positec Power Tools Europe Ltd v Husqvarna AB [2016] EWHC 1061 (Pat); Cantel Medical (UK) Ltd v Arc Medical Design Ltd [2018] EWHC 345 (Pat)).

Intermediate conclusion

55 The Enlarged Board concludes from these considerations that the principle of free evaluation of evidence qualifies as a universally applicable principle in assessing any means of evidence by a board of appeal.

56 Hence, evidence submitted by a patent applicant or proprietor to prove a technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date.

57 This, however, does not immediately lead to the answering of referred question 1 in the negative, without needing to turn to referred questions 2 and 3 because they are dependent on an affirmative answer to referred question 1. Notwithstanding the specific drafting of the referred questions, the Enlarged Board accepts that the gist of the matter underlying the

present referral extends beyond the literal wording of question 1.

58 The Enlarged Board considers the conceptional notion inherent in the term "plausibility", which is often used as a generic catchword, as not being a distinct condition of patentability and patent validity, but a criterion for the reliance on a purported technical effect. In this sense, it is not a specific exception to the principle of free evaluation of evidence but rather an assertion of fact and something that a patent applicant or proprietor must demonstrate in order to validly rely on an asserted but contested technical effect. It appears to the Enlarged Board that the parties, the President of the EPO and the majority of third parties have a similar understanding.

59 As suggested by the parties and the President of the EPO, the Enlarged Board acknowledges a need to provide guidance on the application of the principle of free evaluation of evidence in respect of such post-published evidence for the reliance on a purported but contested technical effect.

Jurisprudence regarding the reliance on a technical effect for inventive step

General considerations

60 Before entering into a discussion of the case law of the boards of appeal, the Enlarged Board takes note of the decision in T 578/06, point 13 of the Reasons, where the board of appeal stated that the EPC required no experimental proof for patentability and considered that the disclosure of experimental data or results in the application as filed and/or post-published evidence was not always required to establish that the claimed subject-matter solved the

objective technical problem. The board of appeal, while referring to T 893/02 and T 1329/04, emphasised in point 15 of the Reasons that this case law considered the establishment of a plausible reliance on a purported technical effect "only relevant when examining inventive step if the case in hand allows the substantiation of doubts about the suitability of the claimed invention to solve the technical problem addressed and when it is thus far from straightforward that the claimed invention solves the formulated problem. This is all the more clear from decisions where an inventive step was in fact denied because the formulated problem was not considered to have been solved."

61 In a number of decisions, the boards of appeal excluded from consideration post-published evidence because the content of the evidence was not available to the skilled person at the relevant date (T 1791/11: as the sole basis for establishing that the application solved the problem it purported to solve; T 125/12: to support an effect that was non-plausible from the application as filed; T 1285/13: the assessment of inventive step was to be made at the effective date of the patent on the basis of the information in the patent together with the common general knowledge then available to the skilled person, post-published evidence filed to support the argument that the claimed subject-matter solved the problem to be solved was taken into account if it was already credible from the disclosure in the patent that the problem is indeed solved; T 2348/13: post-published articles D42 and D43 did not illustrate common general knowledge; T 488/16: As the post-published documents were the first disclosure showing that the purported technical problem had actually been solved, these documents were therefore not taken into consideration in the assessment of inventive step; T 1099/19: The claimed technical effect was not made plausible at the effective date of the patent, and the post-published

documents were not taken into account as they were the first disclosure going beyond speculation).

62 There are also decisions by which the competent board of appeal considered post-published evidence submitted in the context of assessing a claimed technical effect, albeit without a different outcome on the issue of inventive step (T 179/16, T 978/16, T 1499/16, T 229/17, T 334/18, T 1306/18).

63 In T 108/09 post-published evidence was taken into account because the board of appeal found that this evidence had not been the only source of information regarding the claimed technical effect so that the data contained therein could be used in the evaluation of whether or not the problem underlying the invention in suit was plausibly solved.

Analysis of the case law

64 The Enlarged Board is aware of the case law cited by the referring board as examples for different approaches to the acceptance of a patent applicant's or patent proprietor's reliance on an asserted technical effect (see points VI.(6) to (8) above and points 13.4 to 13.6 of the Reasons for the referring decision). As the volume of decisions on the relevance of post-published evidence, such as experimental data, to prove an alleged technical effect for acknowledgement of inventive step in the context of Article 56 EPC is too big to discuss in detail, the Enlarged Board focusses on a selection of in particular more recent jurisprudence, which the development of the earlier case law appears to culminate in.

65 In T 31/18, point 2.5.2 of the Reasons, which was categorised by the referring board as type III case law (see point 13.6 of the Reasons for the referring decision, also referring to

T 2371/13, point 6.1.2 of the Reasons), the board of appeal held that the technical effect relied upon for inventive step according to the problem-solution approach must either be explicitly mentioned in the application as filed or at least be derivable therefrom, but not necessarily originally supported by experimental evidence. It could not be expected from a patent applicant to include an extensive amount of experimental evidence corresponding to all technical features which could possibly be claimed in the application as filed and which could possibly constitute a future distinguishing feature over the closest prior art, since said closest prior art and its technical disclosure may not be known to the applicant at the filing date of the application.

Decisions referred to as type I case law

66 Decision T 1329/04 is mentioned by the referring board as a key example for the conceptional notion underlying referred question 2 (type I, see point 13.4 of the Reasons for the referring decision). The board of appeal in T 1329/04 did not take into consideration post-published evidence and ultimately denied an inventive step of the claimed subject-matter because the application as originally filed lacked enough evidence to make it at least plausible that a solution had been found to the purportedly solved problem. The relevant reasoning is to be found in points 10 and 11 of the Reasons (emphasis added):

"[…] in the application […], it is admitted that "[…], the sequence of GDF-9 is significantly diverged from those of other family members". Yet, functions of members of the TGF-Beta superfamily previously isolated from ovarian follicular fluid (inhibins) or shown to inhibit ovarian cancer (MIS) are recited, and tentatively and presumptively attributed to GDF-9. Further putative roles are also suggested for GDF-9 which cover some of the effects observed with TGF-Beta […] Therefore, the issue here is rather how much weight can be given to speculations in the application in the framework of

assessing inventive step, which assessment requires that facts be established before starting the relevant reasoning. In the board's judgment, enumerating any and all putative functions of a given compound is not the same as providing technical evidence as regard a specific one. **Accordingly, as a significant structural feature fails to be identical in TGF-9 and the members of the TGF- Beta superfamily, and no functional characterisation of TGF-9 is forthcoming in the application, it is concluded that the application does not sufficiently identify this factor as a member of this family i.e. that there is not enough evidence in the application to make at least plausible that a solution was found to the problem which was purportedly solved.**"

67 According to T 235/13, T 787/14, T 488/16, T 2200/17, T 377/18, T 391/18 and T 1442/18, post-published evidence can be taken into account in support of a technical effect that was considered by the competent board of appeal plausible already from the application as originally filed. The following passages from the aforementioned decisions appear decisive for the particular board of appeal for its findings:

T 235/13, point 2.6 of the Reasons:

"[…] the present application […] fails to indicate, in either the disclosure of the invention or the discussion of the prior art, any improvement to a therapy, let alone improved bioavailability of the therapeutic compound. Hence, this further effect does change the character of the invention and for this very reason cannot be taken into account."

T 787/14, points 19 to 21 and 23 of the Reasons (emphasis added):

"**Thus, from the information provided in the patent for clinical trial V59P2, the skilled person cannot conclude that the patients were pre-immunised at least six months previously and within 1 year of the patient's birth with a conjugate of a capsular saccharide of an organism other than N. meningitidis and a diphtheria toxoid or CRM197** […]. Accordingly, any advantageous effect of the composition that may be seen in clinical trial V59P2 cannot be taken into account in assessing inventive step. Nor can the appellant rely on post-published documents […]: The assessment of inventive step is to be made at the effective date of the patent on the basis of the information in the patent together with the common general knowledge then available to the skilled person. The verification of whether or not the claimed solution actually solves the problem, i.e. whether

the claimed subject-matter actually provides the desired effect, must be based on the data in the application in order to avoid that an invention is based on knowledge available after the effective date only. Post-published evidence to support that the claimed subject-matter solves the underlying technical problem can only be taken into account if it is already credible from the disclosure in the patent that the problem is indeed solved. […]
The board concludes from the above analysis that the problem to be solved cannot be defined as put forward by the appellant, namely as the provision of an improved composition, which induces a better immune response to each of the serogroups. […]
Notwithstanding this, in the board's view the skilled person would have no reason to doubt that the claimed composition also induced a boostable immune response in these patients, since there was no prejudice in the art that pre-immunisation with diphtheria toxoid or CRM197 would result in carrier suppression, […].”

T 488/16, points 4.5, 4.9 and 4.19 of the Reasons (emphasis added):

“In the board's judgement, a mere verbal statement that "compounds have been found active" in the absence of any verifiable technical evidence is not sufficient to render it credible that the technical problem the application purports to solve […] is indeed solved, in particular in the present case, where the invention is directed to a very broadly defined class of compounds encompassing millions of structurally rather different candidates with unknown properties, where even the examples show a broad structural variation and where it is inherently unlikely for any skilled person that all of the compounds of the invention or at least a substantial amount of them will exhibit the alleged PTK inhibitory activity. **In the present case, there is also no evidence on file showing that, at the date of filing, the skilled person was in the possession of common general knowledge which, even in the absence of data, made it plausible that the compounds of the invention, in particular dasatinib, could be expected to show PTK inhibitory activity. The appellant's argument that a number of structurally different compounds are known as PTK inhibitors and are in clinical trials or near clinical development […] is not pertinent in this context, as no conclusion with regard to PTK inhibitory activity of dasatinib can be drawn from this knowledge in the absence of any correlation between structural features and function.** […]
[T]he post-published document (9) […] does not merely confirm the technical effect, but rather discloses a specific PTK profile, which identifies dasatinib as an inhibitor with

potent anti-tumour activity […]. No such disclosure is present in the application as filed. […]
[T]he post-published documents (9) and (10) are the first disclosure showing that at least for certain thiazole, in particular dasatinib, the purported technical problem has actually been solved. In accordance with established case law, these documents are therefore not taken into consideration in the assessment of inventive step."

T 2200/17, point 9.6 of the Reasons:

"In the context of whether or not the respondent was allowed to rely on post-published evidence […], appellant 1 contested during the oral proceedings that the application as filed had made it plausible that the claimed compound led to an enhanced parent drug enrichment over D4. However, what matters here is an enhanced parent drug enrichment over TD and TDF rather than D4. Furthermore, the application as filed contains the same examples 9 to 11 as present in the patent. The conclusion above that the patent shows and thus makes it plausible that the claimed compound leads to enhanced potency and parent drug enrichment over TD and TDF thus applies to the application as filed as well. Hence, appellant 1's argument must fail."

T 377/18, point 3.3.1 of the Reasons:

"Document (14) is thus treated as a post-published document. According to the respondent, this document shows that "regorafenib was even effective in patients who showed insufficient response to the treatment with sorafenib" (entry 42 of document (5)). The appellant stated that document (14) did not show superiority of regorafenib over sorafenib. […] However, in the absence of any indication in the application as filed that regorafenib could be used upon failure of treatment with other actives of the same chemical class, i.e. diaryl ureas discussed in the background section with reference to document (5), such post-published evidence cannot be taken into account for assessing inventive step."

T 391/18, points 83 and 8.4 of the Reasons:

"[D26] disclosed the results of a phase III clinical test designated as C209 […] which compared two treatments of HIV infection that were administered once daily. […] In short, D26 showed that a treatment according to claim 1, in which the NNRTI (E-TMC278) is administered at a dose of 25 mg, is equivalent in terms of efficacy and safety to a treatment as disclosed in D15, in which the NNRTI (efavirenz) is administered at a dose of 600 mg. It is therefore apparent that the treatment according to claim 1 involves a considerably lower pill burden than the one of the closest prior art. […] D26 proves that a combination of TMC278,

emtricitabine and tenofovir disoproxil fumarate has a considerably reduced pill burden compared to a therapeutically equivalent combination of efavirenz, emtricitabine and tenofovir disoproxil fumarate. […] Based on the above, the board concludes that, in line with the indications in the patent in paragraphs [0003], [0009] and [0012], the objective technical problem is the provision of an effective and safe treatment of HIV infection in a once-daily administration regime, where the treatment has reduced pill burden. The board is satisfied that the subject-matter of claim 1 solves the problem."

T 1442/18, point 7.1 of the Reasons:

"Entgegen dem Vorbringen der Beschwerdeführerin hält es die Kammer daher für plausibel, dass eine sich auf eine oder mehrere dieser Eigenschaften stützende Erfindung schon am Anmeldetag des Streitpatents gemacht worden war. In diesem Zusammenhang eingereichte nachveröffentlichte Dokumente der Beschwerdegegnerinnen sind daher vorliegend bei der Beurteilung der erfinderischen Tätigkeit zu berücksichtigen."

68 There are also decisions in which post-published evidence was not taken into account because that evidence was regarded as the sole basis for establishing that the technical problem was indeed solved. Post-published evidence filed to support the argument that the claimed subject-matter solved the problem to be solved could only be taken into account if this was already credible from the disclosure in the patent:

T 415/11, points 51 and 54 of the Reasons:

"The present circumstances are that (i) there are no indications either in the patent or in the prior art that the stability of a MenC polysaccharide-containing formulation is improved by sucrose and an amorphous organic buffer and that (ii) the patent indicates that stability problems are caused by proteins.[…]
Besides the argument that the technical problem is not solved, no further arguments were submitted by the parties, for example as to the reformulation of the technical problem or as to whether or not a reformulated, solved problem could be considered as obvious in view of the prior art."

T 1791/11, points 3.2.6 and 3.2.7 of the Reasons (emphasis added):

"[…] **[T]he patent does not provide any experimental data concerning the claimed variants (or any of the many listed variants) and thus no functional characterisation of the**

variants by an alleged advantage should be taken into account when formulating the technical problem. Otherwise, if the technical problem was formulated to include any such advantage, then it would, in the absence of any experimental data in the patent application, not be possible to conclude that such problem had been plausibly solved: this would thus require reformulating the technical problem in a less ambitious manner, resulting in the problem as formulated by the board.
The post-published experimental data of D10, which indeed shows that the claimed variants have better wash performance than the parent BLSAVI (Table 2), could only be taken into account if it just served to confirm what had been rendered plausible by the patent application. […] As discussed above […], it is apparent from the patent application itself that it was not yet known which variants solved the problem and that a test still had to be performed to confirm the alleged advantage. The board thus comes to the conclusion that the patent does not render it plausible that the claimed subject-matter solves the technical problem as formulated by the appellant-proprietor, and the experimental post-published evidence of D10 is in fact the sole basis allowing to conclude that said problem has been plausibly solved."

T 1322/17, point 4.4.7 of the Reasons:

"Since a technical effect related to higher fracture reduction has not been made plausible for the specific dose of 150 mg ibandronic acid administered in any dosing interval in the application as filed, post-published evidence, in the present case document (22), cannot be taken into consideration. […] The post-published data thus does not confirm a statement made in the description, but relates to technical effects based, at least partially, on technical features that have not been disclosed to be linked to the effect under consideration."

Decisions referred to as type II case law

69 Examples of decisions taking post-published evidence into consideration only if the skilled person at the filing date of the patent application in suit would have seen no reason to consider the effect implausible, as underlying referred question 3 (type II, see point 13.4 of the Reasons for the referring decision) are T 536/07, T 1642/07, T 1677/11, T 919/15, T 2097/15, T 184/16 and T 2015/20.

T 536/07, points 9 and 11 of the Reasons:

"Although there are no working examples for the claimed subject-matter in the contested patent and it is not disclosed as a preferred embodiment of the invention, there is a priori no reason for the skilled person to consider it not to be a plausible solution to the above mentioned technical problem. There is also post-published evidence on file demonstrating the feasibility of the proposed solution (cf. documents D21 and D22).
The present situation differs from that underlying decision T 1329/04 of 28 June 2005, wherein the then competent board decided that the claimed subject-matter did not provide a plausible solution to the identified technical problem. […] In the present case, there is no indication whatsoever of a possible prejudice in the art or of foreseen difficulties in carrying out the proposed solution. Although the claimed subject-matter is not disclosed as a preferred embodiment in the contested patent, no further information is found in the post-published evidence that was not already made available to the skilled person by the contested patent […]."

T 1642/07, points 18, 21 and 22 of the Reasons (emphasis added):

"[…] However, the board observes that there is no requirement in the EPC, let alone in Article 56 EPC, that a patent application should include experimental evidence in support of patentability or a claimed technical effect. Hence, the fact that the disclosure in a patent application is merely theoretical and not supported by experimental data is in itself no bar to patentability or to the presence of a technical effect being acknowledged.
The board observes that such a dichotomy arose between, on the one hand, the disclosure in the patent application underlying decision T 1329/04 (lack of the seven cystein residues with their peculiar spacing required for a protein (in that case, GDF-9) to belong to the TGF-beta superfamily - see T 1329/04, point 7 of the reasons- and the lack of functional characterisation of GDF-9 -see ibidem, point 9 of the reasons-) and, on the other hand, the teaching in post-published document (4) that GDF-9 was indeed a growth differentiation factor (see T 1329/04, point 12 of the reasons). Hence, the then competent board concluded that there was not enough evidence in the application as filed to make it at least plausible that a solution had been found to the problem alleged to be solved.
In summary, the negative arguments produced by the examining division no longer apply to the less demanding problem set out in point 13 supra. The board sees also no grounds for doubting that the combined administration of HSV and a chemotherapeutic agent inducing DNA damage is able to achieve

an increase of the level of cell killing above that seen for a treatment modality alone. Under these circumstances, post-published documents […] can be taken into account."

T 1677/11, point 9.5 of the Reasons (emphasis added):

"However, the facts of the present case differ substantially from those underlying decision T 1329/04. […] In contrast, in the present case, the structure of the claimed sodium salt of (-)-omeprazole is fully consistent with that of the known class of gastric acid secretion inhibitors. This clearly differs from the situation in T 1329/04 where the structural features of the polypeptide were found to be inconsistent with that expected of the superfamily.[…] When presented with this information, the board can see no reason a priori for the skilled person to regard it as being implausible, and no arguments were advanced to this effect. […] **In the patent in suit, a consistent and verifiable disclosure is provided of the essential elements of a specific structure and corresponding therapeutic benefit.** Under these circumstances, the board considers it to be appropriate to take into account the post-published evidence submitted for the purpose of assessing whether or not the effect identified is indeed observed."

T 919/15, point 5.6 of the Reasons:

"Der Kammer ist daher nicht ersichtlich, weshalb es dem Fachmann nach dem Studium der ursprünglichen Anmeldung nicht plausibel sein sollte, dass zwischen den in Anspruch 1 genannten Herbiziden (A) und (B) ein Synergismus auftreten kann. Argumente in dieser Hinsicht hat die Einsprechende 3 auch nicht vorgebracht. […] Somit kann ohne gegenteilige Anhaltspunkte im allgemeinen Fachwissen für das Herbizid (A) enthaltende Herbizidkombinationen gerade nicht davon ausgegangen werden, dass ein Synergismus zwischen den in der ursprünglichen Anmeldung nicht getesteten Kombinationen per se unplausibel wäre.[…] Aus den oben genannten Gründen erkennt die Kammer im vorliegenden Fall an, dass ein Synergismus plausibel erscheint. Daher werden die nachveröffentlichten Dokumente […] von der Kammer bei der Beurteilung der erfinderischen Tätigkeit berücksichtigt."

T 2097/15, points 2.2 and 2.2.2 of the Reasons:

"In der ursprünglichen Anmeldung und in den Versuchsberichten D19 und D20 hat die Patentinhaberin gezeigt, dass die Kombination von Glufosinate-ammonium, d.h. einem Herbizid (A) gemäß Anspruch 1, mit jedem der in Anspruch 1 genannten Herbizide (B) unter definierten Bedingungen synergistisch wirkt. […]
In Analogie zu T 919/15 kann daher ohne gegenteilige Anhaltspunkte im allgemeinen Fachwissen für das Herbizid (A)

enthaltende Herbizidkombinationen nicht davon ausgegangen werden, dass ein Synergismus zwischen den in der ursprünglichen Anmeldung nicht getesteten Kombinationen per se unplausibel wäre. Aus den oben genannten Gründen erscheint ein Synergismus plausibel. Die nachveröffentlichten Dokumente […] werden daher bei der Beurteilung der erfinderischen Tätigkeit berücksichtigt."

T 184/16, points 2.5 to 2.9 of the Reasons:

"In the present case, the application as filed does not contain any experimental evidence as regards the disputed plausibility, i.e. the plausibility of the claimed compounds being SGLT2 inhibitors. It is thus necessary to determine whether plausibility can nevertheless be acknowledged in view of the common general knowledge and the prior art.
The board has no indication, nor has the appellant argued that there exists any, that there is prima facie any serious doubt that the claimed therapeutic effect can be obtained. Furthermore, there is no a priori reason or any indication in the common general knowledge that the claimed therapeutic effect cannot be obtained.
[…] In view of the above, the board considers it plausible that the therapeutic effect defined in claim 12 is indeed obtained.
The present case differs from T 1329/04 (points 11-12), in which plausibility was not accepted [in which plausibility was denied] and post-published evidence not taken into account.
In view of this, the post-published evidence D4 can be taken into consideration to support the disclosure in the patent application."

T 2015/20, points 2.6, 2.7 and 5 of the Reasons (emphasis added):

"Section II.C.7.2 of the Case Law of the Boards of Appeal […] presents the considerations set out in T 609/02 and the jurisprudence that followed this decision.[…] Notably, neither T 609/02 nor the jurisprudence that developed from this decision signal a deviation from the established jurisprudence or an interpretation differing from the Guidelines, in particular with respect to the precondition of serious doubts for a convincing argument of lack of sufficiency.
[…] **In this context the Board considers the statement in the application, that the treatment of respiratory disorders, particularly asthma and COPD, with aclidinium is most effective upon administration by inhalation in a dosage of about 400 myg metered nominal dose […] to represent a significant technical teaching, which is far from an invitation to perform a research programme and which does not**

> **prima facie lack plausibility.** This teaching is as such falsifiable, in the sense that it is open to challenge, and is therefore considered to represent information in the form of a specific technical contribution which goes beyond some insufficient verbal statement. In line with the established jurisprudence as discussed […] above the sufficiency of the disclosure of the claimed invention is therefore not to be denied following the Board's assessment as set out […] above, that no serious doubts have come about with respect to the defined utility.
> […] [T]he approaches developed in the jurisprudence of the Boards of Appeal of the EPO for the assessment of sufficiency of disclosure and inventive step specifically take account of the technical contribution actually disclosed in a patent application to avoid patent protection resulting from unreasonable speculation on the basis of propositions that are prima facie implausible."

Intermediate conclusion

70 The Enlarged Board takes note of the classification done by the referring board in respect of the case law of the boards of appeal concerning the relevance of post-published evidence to prove an asserted technical effect for acknowledgement of inventive step (see points 13.4 to 13.6 of the Reasons for the referring decision).

71 However, when analysing the case law in more detail and irrespective of the conceptual terminologies for what questions 2 and 3 refer to as two distinct plausibility approaches, the Enlarged Board understands from the case law of the boards of appeal as common ground that the core issue rests with the question of what the skilled person, with the common general knowledge in mind, understands at the filing date from the application as originally filed as the technical teaching of the claimed invention.

72 Applying this understanding to the aforementioned decisions, not in reviewing them but in an attempt to test the Enlarged

Board's understanding, the Enlarged Board is satisfied that the outcome in each particular case would not have been different from the actual finding of the respective board of appeal. Irrespective of the use of the terminological notion of plausibility, the cited decisions appear to show that the particular board of appeal focussed on the question whether or not the technical effect relied upon by the patent applicant or proprietor was derivable for the person skilled in the art from the technical teaching of the application documents.

Considerations concerning the jurisprudence regarding sufficiency of disclosure

73 As noted in points 11 and 12 above, the referred questions do not require an answer to the issue of sufficiency of disclosure and Article 83 EPC. However, as the terminological notion of plausibility relied upon by the referring board in questions 2 and 3 of the referral and the reasons for it is mainly to be found in the case law of the boards of appeal with regard to the patentability requirement of sufficiency of disclosure, the Enlarged Board accepts the appropriateness of a comparative analysis and comparative considerations in this regard.

74 While the issues of sufficiency of disclosure (Article 83 EPC) and inventive step (Article 56 EPC) and their assessment are clearly to be treated separately and on their own, as correctly pointed out by the referring board in point 13.3.1 of the Reasons of the referring decision, the Enlarged Board is aware of the case law in particular concerning second medical use claims where the notion of "plausibility" has been used. For such claims, the issue of reliance on post-

published evidence for a purported technical effect arises in particular in the context of sufficiency of disclosure.

Indeed, a technical effect, which in the case of for example a second medical use claim is usually a therapeutic effect, is a feature of the claim, so that the issue of whether it has been shown that this effect is achieved is a question of sufficiency of disclosure under Article 83 EPC.

Hence, because the subject-matter of second medical use claims is commonly limited to a known therapeutic agent for use in a new therapeutic application, it is necessary that the patent at the date of its filing renders it credible that the known therapeutic agent, i.e. the product, is suitable for the claimed therapeutic application. The Enlarged Board explained the legal and historical background to the patentability of further medical uses in its decision G 2/08.

75 In decision T 609/02 (points 5 to 9 of the Reasons, emphasis added), cited by the referring board and in some decisions discussed in the context of inventive step, the board of appeal reasoned its finding on lack of sufficiency of disclosure:

"The patent specification provides no evidence at all relating to the invention in claim 6 […]
The appellant provided post-published evidence showing that steroid hormones such as needed to carry out the use according to claim 6 were later structurally identified and that they, indeed, have an effect on AP-1 stimulated transcription. […]
On the basis of the disclosures of these post-published documents, it was argued by the appellant that by carrying out the claimed invention, one would necessarily obtain pharmaceutical compositions since it was by following the teachings of the patent in suit that the post-published results had been obtained. Consequently, in the appellant's opinion, sufficiency of disclosure had to be acknowledged.
The board cannot share this opinion. Sufficiency of disclosure must be satisfied at the effective date of the patent, ie on the basis of the information in the patent application together with the common general knowledge then available to the skilled person. Acknowledging sufficiency of

disclosure on the basis of relevant technical information produced only after this date would lead to granting a patent for a technical teaching which was achieved, and, thus, for an invention which was made, at a date later than the effective date of the patent. The general principle that the extent of monopoly conferred by a patent should correspond to, and be justified by, the technical contribution to the art, has to be kept in mind […].
[…] **It is required that the patent provides some information in the form of, for example, experimental tests, to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se.** […] Once this evidence is available from the patent application, then post-published (so-called) expert evidence (if any) may be taken into account, but only to back-up the findings in the patent application in relation to the use of the ingredient as a pharmaceutical, and not to establish sufficiency of disclosure on their own."

76 Other examples for decisions in line with T 609/02 can be found in the following cases:

T 1599/06, points 6, 7.1, 7.2 and 8 of the Reasons (emphasis added):

"[…] if a therapeutic application is to be accepted as sufficiently disclosed, **the application or the patent, respectively, and/or the common general knowledge has to provide some information rendering it technically plausible for the skilled person that the claimed compounds can be applied for the claimed therapeutic use** (T 219/01 of 15 December 2004; T 609/02 of 27 October 2004)[…]
In the decision under appeal the examining division considered that no conclusion could be drawn from data in the application demonstrating an immunoprotective effect for the 30 kDa protein or the 32A kDa protein. It supported its view by referring to evidence in document D1 describing differing immunological properties of the 30 kDa and the 32A kDa proteins in a skin test for assaying the induction of delayed-type hypersensitivity[…]
However, the authors of document D1 see a possible reason for this difference in the fact that the 32A kDa protein is "more efficiently released from the bacilli, and the dose of this antigen may therefore be markedly reduced by use of killed cells for sensitization"(page 381, left-hand column). Thus, the failure to induce a reaction is not necessarily ascribable to the immunological capabilities of the protein, but to the low quantities present in the killed bacteria used for sensitisation. Hence, in the board's view, the results in

document D1 pointed to by the examining division are not conclusive evidence of a difference in the immunological reactivities of the two proteins. Therefore, the extrapolability of data in the application concerning the immunoprotective effect of the 30 kDa protein to the 32A kDa protein cannot be called into doubt by the disclosure in document D1."

T 754/11, point 25 of the Reasons (emphasis added):

"As stated by the opposition division […], the provision of experimental evidence for the claimed medical uses is not necessary as long as the underlying physiological mechanisms make such use plausible (cf. inter alia, T 609/02 of 27 October 2004, point 9 of the "Reasons for the Decision"). Target-specific RNA degradation is sufficiently disclosed in Examples 1 to 3 of the patent application to make also credible the target-specific degradation of the disease-associated RNAs mentioned in claims 13 to 16. **Furthermore, page 8, line 30, to page 9, line 26, provide guidance on how to prepare a composition for therapeutic applications.** Finally, there is also ample post-published evidence on file to confirm this conclusion (cf. inter alia, page 159, Table 1 of document D36). This evidence can be taken into account because it only supports the findings and disclosure of the patent (cf. T 609/02, supra)."

T 760/12, point 3.3, 3.10 and 3.15 of the Reasons (emphasis added):

"These [claims 6 and 7] being second medical use claims, the technical effect, which is the therapeutic effect, is expressed in the claim. When the technical effect is expressed in the claim, the issue of whether this effect is indeed achieved over the whole scope of the claim is a question of sufficiency of disclosure (G 1/03, OJ 2004, 413, Reasons 2.5.2). Hence, under Article 83 EPC, unless this is already known to the skilled person at the priority date, the application must disclose the suitability of the product to be manufactured for the claimed therapeutic application (T 609/02, Reasons 9). Thus, in order to establish whether the requirement of sufficiency of disclosure is met, **it has to be assessed whether the application discloses the potential suitability of the substance as defined in the claim** to exert a therapeutic effect on a tumour or angiogenesis-related disorder which is associated with activation of c-met.[…]
Hence, the patent essentially teaches to antagonise the beta chain in order to interfere with c-met activation, but this teaching was already derivable from the prior art, including D5, which had disclosed that the beta subunit of HGF was "crucial for the optimum activation of Met receptor induced

by HGF/SF" (D5, page 7446, right column, lines 11 to 13). However, the patent does not demonstrate that any monoclonal antibody with the functional characteristics as defined in the claim (binding to activated HGF beta chain and inhibiting the binding of said activated HGF beta chain to c-met) would inhibit c-met activation. The skilled person would thus have to embark on a research programme without any teaching in the application on how to achieve the desired effect of inhibiting c-met activation with a single monoclonal antibody (T 1466/05, Reasons 16). Hence the board concludes that it is not sufficiently disclosed in the patent that a single monoclonal antibody as defined in the claim potentially exerts the therapeutic effect as claimed.[…]
As to D30 and D41, these are post-published documents and hence not available to the skilled person at the effective date of the patent. Moreover, they do not establish that the teachings of the patent enabled the production of antibodies with the functional characteristics as claimed, in particular the claimed therapeutic effect, because the antibodies disclosed therein are not directed against the activated beta chain."

T 895/13, points 15 to 18 of the Reasons (emphasis added):

"However, as a matter of fact, the claimed vaccine which is based on tetanus toxoid as the carrier has not been exemplified in the patent. No data are reported in the patent for meningococcal conjugates using tetanus toxoid as the carrier.
In view of the well-established phenomenon of carrier suppression, in particular in the context of tetanus toxoid […], and the known unpredictability of carrier suppression in the context of conjugate vaccines ([…], **the results obtained in the patent with CRM197 as the carrier do not make it plausible that meningococcal conjugates using tetanus toxoid as the carrier are suitable for the successful immunisation of patients that had been pre-immunised with tetanus toxoid. Under these circumstances, post-published evidence cannot be taken into account for the establishment of sufficiency of disclosure** […].
In view of the above considerations and in the light of decision T 609/02, the subject-matter of claim 1 of the main request fails to meet the requirements of Article 83 EPC and the request is therefore not allowable."

T 1045/13, points 3.2 and 3.3 of the Reasons (emphasis added):

"To sum up, the appellant has chosen to rely solely on experimental evidence in support of the therapeutic treatment as claimed in claim 1. **The experimental evidence on file fails however to provide evidence for the effects claimed.**

The examples do not cover the whole scope of the claim and do not provide evidence of therapeutic efficacy that meets scientific standards (statistically significant number of patients, control group). Effective treatment of the medical conditions under consideration has thus not been shown. Consequently, the board comes to the conclusion that the subject-matter of claim 1 is not sufficiently disclosed (Article 83 EPC).”

T 2059/13, points 4.5.3 and 4.6 of the Reasons (emphasis added):

“For these reasons, there is no evidence on file showing that the person skilled in the art was in the possession of common general knowledge at the filing date of the patent in suit which, together with the disclosure of the application as filed, led to the direct and unambiguous conclusion that 5-HT1A agonists in general, or any of the compounds of formula (1) in particular, were useful in the treatment of any type of bipolar disorder.
Hence, **the application as filed in combination with the common knowledge at the filing date did not disclose the suitability of any of the compounds of formula (1) in the treatment** of any type of bipolar disorder. Consequently, the minimum requirements set out in T 609/02 for taking into account post-published evidence are not met.”

T 887/14, points 3.6.11 to 3.6.13 of the Reasons:

“With regard to whether it is plausible that other macrocyclic lactones of the same class recited in claim 1 would also share synergy with spinosad, the board notes that the patent itself provides a plausible mechanistic explanation of why this would be the case […]. In the absence of any evidence to the contrary, the board sees no reason not to accept this as a reasonable assumption. The board also sees no reason to reject said explanation due to the lack of in vivo data in the patent, as argued by the appellant, since as mentioned above, the in vitro test according to example 2 thereof may be considered in vivo at least as far as the fleas are concerned.
In view of the above, the tests of example 2 of the patent, D12, D13, D14, D15 and D26 plausibly demonstrate that synergy is present in the majority of ratios tested, the only concrete exception being the 1:1 ratio described in D12 (see "Conclusions") which is said to "reflect a purely additive interaction" (between spinosad and milbemycin).
Consequently the board is in no doubt that it would be within the routine ability of the skilled person to arrive at appropriate synergistic ratios of spinosad to the specific macrolactone recited in claim 1 without undue burden.”

T 321/15, points 3.2.5 and 3.3 of the Reasons (emphasis added):

"Taking all these facts together, the board acknowledges that at the priority date of the patent in suit the administration to infants at risk of developing obesity later in life of the claimed nutritional composition could plausibly/credibly achieve the claimed therapeutic effects. With respect to the post-published D15 and D16, they need not be taken into account for the assessment of sufficiency of disclosure, more specifically the suitability of the claimed nutritional compositions for the achievement of the claimed therapeutic effects. According to the case law of the boards of appeal of the EPO, such **post-published documents can only confirm the expectations of the skilled person reading the patent in suit and having knowledge of the prior-art documents** D1 and D2 (T 609/02, points 9 and 13 of the Reasons). Whether these documents indeed confirm the reasonable expectations of the skilled person can be left undecided since the board is already convinced of the invoked plausibility as stated above."

T 1680/17, point 3 of the Reasons (emphasis added):

"Consequently, **the data presented in the application as filed and depicted in the published patent renders it plausible that the claimed composition is suitable for use in the treatment of breast cancer.** Post-published evidence, in the form of document (35), was filed as confirmation. Hence, the invention as defined in the claims is sufficiently disclosed in the patent and the ground for opposition under Article 100(b) EPC does not prejudice the maintenance of the patent."

T 1571/19, points 1.2 and 1.16 of the Reasons (emphasis added):

"**Attaining the claimed therapeutic effects is a functional technical feature characterising claim 1.** Thus, in order to meet the requirement of sufficiency of disclosure, the patent must render it plausible that the claimed feed composition is suitable for treating the diseases indicated in the claim […]

For these reasons, and considering the fact that the content of n-3 fatty acids, EPA in particular, was considerably higher in the CMS diet than in the reference diet, it is plausible that, as postulated in paragraphs [0009], [0010], [0011] and [0061] of the opposed patent, compositions comprising n-3 fatty acids in the claimed proportions are suitable for treating and preventing the relevant disorders. […] However, there is no evidence that the skilled person, relying on the information given in the opposed patent and on

common general knowledge, would not have been able to prepare a composition as described in claim 1 which is suitable for treating the relevant diseases. It has thus been concluded that the claimed invention is sufficiently disclosed (Article 83 EPC).”

Intermediate conclusion

77 The reasoned findings of the boards of appeal in the decisions referred to above make clear that the scope of reliance on post published evidence is much narrower under sufficiency of disclosure (Article 83 EPC) compared to the situation under inventive step (Article 56 EPC). In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, the proof of a claimed therapeutic effect has to be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved. A lack in this respect cannot be remedied by post-published evidence.

National legal framework and jurisprudence with regard to the reliance on a technical effect for inventive step

78 While according to the AIPPI 2019 Study on plausibility none of the statutory framework of the EPC Contracting States referred to in the following contain an explicit patentability requirement for what the referring decision in questions 2 and 3 refers to as plausibility concepts (see group reports for Switzerland, Germany, France, United Kingdom (England and Wales) and The Netherlands), the Enlarged Board is aware of the respective national jurisprudence and literature. In the following, the different

approaches concerning the reliance on an asserted technical effect for inventive step and the relevance of post-published evidence have been identified by way of examples.

Switzerland

79 The Swiss courts have apparently not developed any specific criterium in this regard, as confirmed in the AIPPI 2019 – Study Question – Plausibility.

The Enlarged Board takes note of the more recent Swiss Federal Court decision (4A_149/2021) in deciding on an appeal against a decision of the Swiss Federal Patent Court, while referring to the case law of the boards of appeal that advantages in formulating the problem to be solved can only be taken into account if the person skilled in the art can derive the purported effect from the documents originally filed against the background of the closest prior art or if this effect is implied in the documents originally filed. In the absence of such an implication, courts may assume that the invention is merely an alternative and not an improvement over the prior art, and that any subsequent attempt by the patent proprietor to prove the invention's originality is irrelevant.

Germany

80 In the German patent law related literature an opinion (see Ackermann, GRUR 2021, 3) is held that German case law does not allow a reliance on post-dated evidence if the advantages shown therein make a significant contribution to the invention or even constitute its core. The objective problem the person skilled in the art is faced with cannot be

influenced by a technical teaching that extends beyond the original disclosure.

In another opinion (T. Exner/A. Hüttermann, GRUR 2018, 97), the case law of the boards of appeal since T 1329/04 was considered; it was noted that the requirement that a claimed effect must be plausible was rather foreign to the classical German understanding.

81 The Enlarged Board understands from the decision *"Erlotinib hydrochloride"* (3 Ni 20/15, point II.3.c.5) of the Reasons) of the German Patent Court, referring to a decision of the boards of appeal (T 390/88) and two decisions of the German Federal Court of Justice (X ZB 3/69 – Anthradipyrazol; X ZB 2/71 – Imidazoline) that post-published evidence for an alleged technical effect can be taken into consideration. The Court considered it sufficient that the subject-matter of the claimed invention actually achieved an improvement in the sense of a therapeutic advance or that a hitherto unmet public need was met on the relevant date. The alleged improvement did not need to be documented on the filing date, rather documents in support of said improvement could be submitted later.

France

82 The pertinent line of case law in France appears to be particularly addressed in the context of sufficiency of the disclosure as a patentability requirement and the field of chemistry, more specifically of medicines (e.g. Cour de cassation, 15-19726 - Merck c/ Teva; Tribunal de Grande Instance de Paris 07/16446 – Teva / Sepracor, and 16/01225 - Ethypharm / MSD; see also AIPPI 2019 Study - Plausibility in the group report for France). Post-published evidence is sometimes taken into account, albeit without any specific

criteria being set out explicitly. Such documents are considered to be relevant in particular when relied upon to support the findings in the patent application, rather than to compensate for an intrinsic deficiency. The vast majority of French case law does not contain any express discussion of criteria linking the admissibility of post-published documents and the notion of "plausibility".

The Netherlands

83 Also the Dutch courts appear to not apply the notion of plausibility as a separate concept but rather discuss this, if necessary, as an element of assessing inventive step of the claimed subject-matter, or of sufficiency of disclosure. In the decision of the Court of Appeal The Hague in case Leo Pharma v Sandoz (200.195.459/01) it was held that the contribution to the state of the art must be assessed from the perspective of the average skilled person at the application date, and that any effects the average skilled person would have considered not plausible at the application date must be disregarded in the context of the assessment of inventive step. The Court stated that there was no general standard of plausibility and that the patent proprietor did not need to provide complete evidence of the alleged effect in the application. However, the statements regarding the effect should not be merely speculative. If the effect was evident for the person having ordinary skill in the art when reading the patent, taking into account their common general knowledge, it was not necessary to disclose and substantiate the technical effect in the application. However, if the effect was not evident for the person having ordinary skill in the art, the threshold for disclosing the effect was higher. A later decision in case Astrazeneca v Sandoz of the Court of Appeal The Hague (200.237.828/01) does not deviate

from this approach, where the Court found that the patent in suit made the alleged effects plausible. However, in the more recent case Bristol-Myers Squibb v Sandoz the District Court The Hague (C/09/627925 / KG ZA 22-326 - Bristol-Myers Squibb Holdings Ireland v Sandoz) appears to refer to what the referring board considered as "type II plausibility" of which it was not convinced with regard to the patent application.

United Kingdom (England and Wales)

84 The High Court decision in Sandoz Ltd and another v Bristol-Myers Squibb Holdings Ireland Unlimited Co and another [2022] EWHC 822 (Pat) provides a summary of the case law on what the referring board discusses under the conceptual terminology of plausibility both before the national courts (Warner-Lambert v Generics [2018] UKSC 56, Fibrogen v Akebia [2021] EWCA Civ 1279) and the boards of appeal (i.a. T 609/02). The approach taken in Warner-Lambert v Generics [2018] has essentially been confirmed in the Court of Appeal decisions Illumina Cambridge Ltd v Latvia MGI Tech SIA and others ([2021] EWCA Civ 1924) and FibroGen Inc. v Akebia Therapeutics Inc. and another company; Astellas Pharma Inc. v Akebia Therapeutics Inc. and other companies ([2021] EWCA Civ 1279).

85 Post-published evidence may be relied upon only to confirm the existence of a technical effect which is plausible in the light of the specification and the skilled person's common general knowledge, and not to establish the existence of a technical effect for the first time (see C. Floyd, GRUR 2021, 185; P. Johnson, GRUR 2019, 524; A. Slade, Intellectual Property Law Quarterly 2020, 180; A.J.K. Wells, Journal of intellectual property law & practice 2019, Vol 14 issue 10, 784; see also from a more critical perspective R. Jacob, Bio-Science Law Review 2020, 17(6), 223;, all with numerous further references). An example where post-published evidence

(data) was considered is the decision of the Supreme Court in Warner-Lambert Company LLC v Generics (UK) Ltd t/a Mylan and another ([2018] UKSC 56), which, however, dealt with the issue of sufficiency of disclosure. In that decision Lord Hodge (point 184 of the decision) held that the plausibility test in the context of sufficiency of disclosure allowed the court to have regard to such later evidence to make good the prediction if there was some basis for the prediction in the patent. He agreed with Floyd LJ in the leading judgment in the Court of Appeal (Warner-Lambert Company LLC v. Generics (UK) Ltd, [2016] EWCA Civ 1006, point 133 and also point 39) and treated the outcome of these tests as fortifying the judge's conclusion that the patent had contained a plausible prediction. Lord Sumption (point 41 of the decision) and two other judges found that such later acquired evidence was admissible only to confirm results rendered plausible by the patent specification. This approach is also to be found in the Patents Court's decisions in Actavis Group PTC EHF & Anr v Eli Lilly & Co ([2015] EWHC 3294 (Pat), point 181 of the decision) and in Saint-Gobain Adfors SAS v 3M Innovative Properties Co ([2022] EWHC 1018 (Pat)). However, there are also examples of decisions where such post-published evidence (data) was not considered, e.g. by the Patent Court in Eli Lilly and Co and other companies v Genentech, Inc ([2019] EWHC 387 (Pat), point 578) and in Generics (UK) Ltd trading as Mylan and another v Yeda Research and Development Company ([2017] EWHC 2629 (Pat), points 197 and 200).

Intermediate conclusion

86 Like the EPC, none of the legal systems of the EPC Contracting States provide for an explicit patentability requirement for what the referring decision discusses and

addresses with what is referred to in questions 2 and 3 under the term "plausibility".

87 Notwithstanding the fact that the aforementioned decisions were taken on the decisive facts of the case in hand and the particular submissions made by the parties to those proceedings, the Enlarged Board recognises a certain degree of common ground that the courts of the EPC Contracting States, when confronted with the examination of an asserted technical effect in the assessment of inventive step and with the question whether a patent proprietor may rely on post-published evidence to confirm that technical effect, ponder on the technical teaching of the claimed subject-matter that the person skilled in the art, with the common general knowledge in mind, understands from the patent application.

Concluding considerations

88 As already mentioned in points 55 to 59 above, the proceedings under the EPC are governed by the principle of free evaluation of evidence which is also known in various EPC Contracting States with a civil law system.

89 The principle of free evaluation of evidence depicts a universally applicable principle of both procedural and substantive law in assessing any means of evidence submitted by a party in proceedings under the EPC, be it an administrative department of the EPO or a board of appeal as the competent judicial body reviewing decisions of such administrative departments pursuant to Article 106(1) EPC.

90 As the principle of free evaluation of evidence is enshrined in the right of each party to proceedings under EPC to give evidence in appropriate form pursuant to Articles 113(1) and 117(1) EPC, it may not be used to disregard evidence *per se*

insofar as it is submitted and relied upon by a party in support of an inference which is challenged as to its plausibility and is decisive for the final decision.

91 Hence, evidence submitted by a patent applicant or proprietor to prove a purported technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date.

92 The term "plausibility" that is found in the case law of the boards of appeal and relied upon by the referring board in questions 2 and 3 of the referral and the reasons for it, does not amount to a distinctive legal concept or a specific patent law requirement under the EPC, in particular under Article 56 and 83 EPC. It rather describes a generic catchword seized in the jurisprudence of the boards of appeal, by some national courts and by users of the European patent system.

93 The relevant standard for the reliance on a purported technical effect when assessing whether or not the claimed subject-matter involves an inventive step concerns the question of what the skilled person, with the common general knowledge in mind, would understand at the filing date from the application as originally filed as the technical teaching of the claimed invention. The technical effect relied upon, even at a later stage, needs to be encompassed by that technical teaching and to embody the same invention, because such an effect does not change the nature of the claimed invention.

94 Hence, 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 consider said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention.

95 The Enlarged Board is aware of the abstractness of some of the aforementioned criteria. However, apart from the fact that the Enlarged Board, in its function assigned to it under Article 112(1) EPC, is not called to decide on a specific case, it is the pertinent circumstances of each case which provide the basis on which a board of appeal or other deciding body is required to judge, and the actual outcome may well to some extent be influenced by the technical field of the claimed invention. Irrespective of the actual circumstances of a particular case, the guiding principles set out above should allow the competent board of appeal or other deciding body to take a decision on whether or not post-published evidence may or may not be relied upon in support of an asserted technical effect when assessing whether or not the claimed subject-matter involves an inventive step.

Order

For these reasons it is decided that the questions of law referred to the Enlarged Board of Appeal are answered as follows:

1. **Evidence submitted by a patent applicant or proprietor to prove a technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date.**

2. **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.**

The Registrar: The Chairman:

N. Michaleczek C. Josefsson

Decision electronically authenticated