

Order
of the Court of First Instance of the Unified Patent Court
Local Division The Hague
issued on 31/07/2024
regarding provisional measures

Headnote: Application for provisional measures. Mushroom strain is not considered to be excluded from patentability (Article 53(b) EPC. Infringement. Measures granted.
Keywords: provisional measures, patentability of mushroom strain; infringement

CLAIMANT

Amycel LLC
(Applicant) - 260 Westgate Drive - 95076 -
Watsonville, California – US

Represented by Hendrik
W.J. Lambers, Daan F. de
Lange and Jasmijn de
Groot

DEFENDANT

██████████
(Defendant) - ██████████ ██████
██████ - ████████ - █████

Represented by Michal Przyluski and
Joanna Dargiewicz

PATENT AT ISSUE

Patent no. *Proprietor/s*

EP 1 993 350 B2 Amycel LLC

PANEL/ DECIDING JUDGES

Presiding judge	Edger Brinkman
Legally qualified judge	Rute Lopes
Technically qualified judge	Steen Wadskov-Hansen
Judge-rapporteur (“JR”)	Margot Kokke

This order has been issued by the panel.

LANGUAGE OF PROCEEDINGS: English

ORDER SOUGHT BY THE PARTIES AND SUBMISSIONS

1. On 14 May 2024, Applicant, hereinafter “Amycel”, filed an application for provisional measures (“the Application”) requesting the court (directly enforceable):

A.

(1) to order an injunction against the defendant, effective as of the day of service on the defendant, to refrain from infringing EP 1 993 350 B2 in any way in the territories of The Netherlands, Germany, France and Italy (art. 63(1) UPCA and R. 211(1)(a) RoP);

(2) alternatively, to order an injunction against the defendant, effective as of the day of service on the defendant, to refrain from infringing EP 1 993 350 B2 in any way, in particular by making, offering, placing on the market and/or using and/or importing or storing for those purposes a hybrid *Agaricus bisporus* mushroom strain BR06, wherein a representative culture of BR06 is available from ATCC under Accession No. PTA-6876, more in particular by making, offering, placing on the market and/or using and/or importing or storing for those purposes the Cayene mushroom strain as specified in the complaint and any other infringing strains, all within the territories of The Netherlands, Germany, France and Italy (Art. 63(1) UPCA and R. 211(1)(a) RoP);

B.

To order the delivery up of products suspected of infringing EP 1 993 350 B2 so as to prevent their entry into or movement within the channels of commerce (R. 211(1)(b) RoP);

C.

To order the defendant, within two weeks after the date of the decision to be rendered in these proceedings, to provide to Amycel (p/a Brinkhof N.V.) a written account with the full names and address details of all customers to whom the defendant offered for sale, sold and/or delivered or otherwise traded in the Cayene strain, or any other product that falls within the scope of protection of EP 1 993 350, within the territories of The Netherlands, Germany, France and Italy (R. 211 (1) RoP);

D.

To order the defendant to pay an interim award of applicant Amycel’s costs (R. 211(1)(d) RoP);

E.

To order the defendant to pay the Court a penalty payment of € 50,000.00 for each day or part of a day that one of the granted aforementioned injunctions under A. are not complied with, and a penalty payment of € 5,000,00 for each day or part of a day that the to be granted order under C. is not complied with in full (R. 354(3) RoP).

2. Amycel asserts that Defendant infringes its rights with his brown mushroom strain sold under the name ‘Cayene’.

3. The Defendant did not file a protective letter. The JR gave the Defendant the opportunity to file a written reply to the Application. He submitted an Objection to the Application on 26 June 2024, including invalidity arguments.
4. The Defendant requests the court:
 - to reject the provisional measures sought;
 - alternatively, in case the measures are not rejected, to order Amycel to provide security in the amount of EUR 200,000.00 according to R. 211.5 RoP;
 - to award costs to the Defendant.
5. Amycel was given the opportunity to reply in writing to invalidity arguments raised in the Objection. Because invalidity of the patent was argued by Defendant, the JR requested the president of the court to allocate a TQJ to the panel, which request was granted.
6. On 9 July 2024 an oral hearing took place in The Hague in hybrid form. In addition to the judges and the above-mentioned representatives, the persons listed below were physically present in the hearing room:

On behalf of Amycel: ██████████ ██████████ Director of Research and Development; ██████████ ██████████ European Sales Manager; Philipp Marchand, Patent Attorney and UPC Representative; ETH Tilmann Künzl, Patent Attorney; ██████████ ██████████ Senior Research Technician, Naktuinbouw.

On behalf of Defendant: Polish attorneys Sebastian Kwiecień and Grzegorz Tylec (no UPC representatives).

One of Amycel's experts, ██████████ ██████████ Director of Computational Biology, Verinomics, participated online via a video-link and via projection on screens in the hearing room. This was also the case for Defendant's expert ██████████ ██████████ Assistant Professor, Institute of Biology of the University of Rzeszów.

7. Before the oral hearing, both parties submitted additional exhibits. A R.109.1 application filed by Defendant requesting the court to provide (simultaneous) interpretation facilities between English and Polish during the oral hearing, was rejected (ORD_35405/2024 of 25 June 2024 in App_35134/2024).

SUMMARY OF THE FACTS

The patent

8. Amycel (currently) owns EP 1 993 350 B2 (hereafter also "the patent" or "EP 350 B2") granted for '*Brown mushrooms for commercial production*'. The grant of the B1 version of the patent was published on 29 June 2016, based on an international application filed on 3 August 2006 (published as WO 2007/019306), claiming priority of 4 August 2005. During opposition proceedings the patent was maintained in amended form (B2 version) which was published on 24 July 2019. There is no appeal pending at the EPO.
9. The text of the only remaining claim of EP 350 B2 in the original English language of the patent is as follows:

1. A hybrid *Agaricus bisporus* mushroom strain BR06, wherein a representative culture of BR06 is available from ATCC under Accession No. PTA-6876.

10. The patent is in force in the following UPC Contracting Member States: The Netherlands, Germany, France and Italy. It is also valid in other, non-UPC, countries, including Poland.

11. The description of the patent contains inter alia the following:

BRIEF SUMMARY OF THE INVENTION

[0010] It is an object of the invention to provide brown varieties of *Agaricus bisporus* mushroom with improved commercial characteristics relative to existing brown commercial mushrooms. Specifically, it is an object of the invention to provide mushrooms that have the following characteristics (relative to brown *Agaricus bisporus* now being marketed):

- Increased productivity
- Darker, more attractive cap color
- Thicker cap
- Non-compatibility with existing strains or antagonism with existing strains (genetic disease barrier).

[0011] These and other objects of the invention have been accomplished by providing a hybrid *Agaricus bisporus* mushroom strain BR06. A representative culture of BR06 is available from ATCC under Accession No. PTA-6876.

DETAILED DESCRIPTION OF THE INVENTION

[0012] The present invention arose from a breeding program that crossed mushrooms derived from commercial *Agaricus bisporus* strains with wild mushroom strains. The specific wild mushroom strain that was eventually found to provide the desired genetic characteristics is known as AA-0096. This wild strain was previously described in the scientific literature because of its unique genetics. Strain AA-0096 is also known as BP-1 and ARP-023 and is available from the American Type Culture Collection (ATCC) under accession number 76562 as a non-patent deposit.

(...)

[0017] (...) It was not until we crossed homokaryons from commercial browns and commercial whites, creating a "bridging cross strain" that we were able to produce darker, more productive mushrooms by introducing the genetic material from AA-0096 via a second cross with the bridging cross strain.

[0019] (...) in order to make possible the preparation of all possible crosses of AA-0096 and the specific bridging cross strain (4x29) developed by the present inventors, strain 4x29 has also been deposited under the provisions of the Budapest Treaty (...)

The parties, market situation and allegedly infringing acts

12. Amycel develops mushroom strains. Amycel sells the mushroom strain BR06, which is mentioned in claim 1 of the patent, as 'Heirloom'. Heirloom is the number one selling brown mushroom strain in the world, including Europe.

13. Defendant is a Polish farmer who grows mushrooms and who operates from Poland using his last name [REDACTED] to distinguish his products. He took over the mushroom production from his father. They have been active in the field of mushroom production since well before 1990. Currently, Defendant is offering for sale various white and brown mushroom strains. One of the brown strains offered for sale by the Defendant is called [REDACTED] 'Cayene' and is sold under this name in Poland since 2017 according to Defendant.

14. Claiming that Defendant infringes the patent in Poland with Cayene, Amycel approached Defendant to try to reach an amicable settlement. When this was unsuccessful, Amycel started proceedings on the merits in Poland in July 2023. These proceedings are still pending.

15. Amycel became aware of sales of Cayene in UPC territory late July 2023. It submitted an invoice of Defendant for sales of (77 boxes of) mycelium of Cayene mushrooms to a customer in The

Netherlands dated 24 July 2023. It managed to obtain samples of Cayene which it sent to specialised laboratories for analysis to verify whether this strain indeed infringes the patent.

16. Pending the action, it submitted another invoice for sales of Cayene in The Netherlands dated 20 May 2024. It concerns 87 and 47 boxes of mycelium that were delivered on 22 May 2024. On the invoice the following is mentioned: “1 box = 30 litre of mushroom spawn GMO FREE”.
17. On the evening before the hearing, Defendant submitted an invalidity action requesting to revoke the patent with the Central Division Milan of the UPC (PR_ACT_40493/2024, UPC_CFI_403/2024).

Technical background and subject of the patent

18. The invention according to the patent concerns the generation of a brown mushroom strain BR06, a representative culture of which is available from ATCC, with improved characteristics vis-a-vis the ‘old fashioned brown’ such as the strain Amycel 2400. The BR06 strain was generated by using three different mushroom strains. First a commercial white mushroom strain (a U1 derivative) was crossed with a commercial brown mushroom strain (Amycel 2400) to create a ‘bridging cross strain’ called 4x29, which in turn was crossed with the wild mushroom strain AA-0096 (patent [0012], [0017] – [0020]).

POINTS AT ISSUE

19. Amycel asserts that Defendant infringes the patent within UPC territory with its brown mushroom strain Cayene. It submitted two invoices of sales in The Netherlands of Cayene (see paragraphs 15 and 16 above). In support of its position that Cayene spawn sold in The Netherlands infringes the patent, it submitted several reports, namely:

- 1) A project report by NakTuinbouw, a Dutch autonomous public body regulated by the ministry of Agriculture, Nature and Food Quality titled “*Genotypic comparison of mushroom strains*”, concerning genetic comparison of fourteen mushroom strains, including the deposited BR06 strain, which is the subject of the patent, Amycel’s Heirloom and Defendant’s Cayene, dated 1 May 2024. NakTuinbouw performed Amplified Fragment Length Polymorphism (“AFLP”) and Whole Genome Sequencing (“WGS”) analysis.

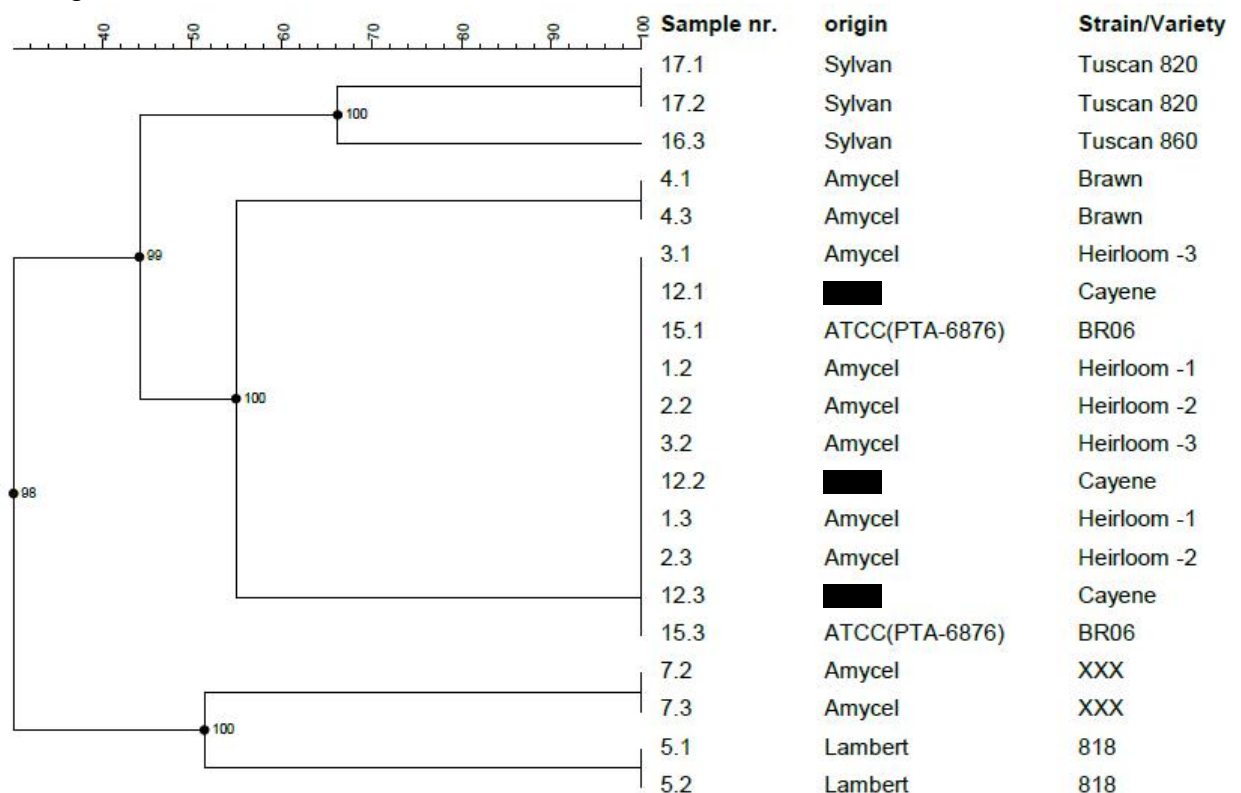
AFLP is a molecular marker technique used in genetic analysis. It combines the techniques of restriction enzyme digestion and PCR (Polymerase Chain Reaction) amplification to detect genetic variation between organisms. The first step of AFLP is DNA fragmentation; in this step the DNA of the organisms being studied is digested/ by restriction enzymes (in this case a combination of EcoRI/MseI was used). Four different primer combinations (PCs) were subsequently applied to all samples for the PCR process. The analysis of the 4 fingerprints generated with the 4PCs resulted in 430 clearly recognizable DNA fragments (monomorphic and polymorphic marker bands together). Since only polymorphic bands have discriminative power and the monomorphic bands do not contribute to the distinction of varieties, only the polymorphic markers were taken into account. As a result, 94 DNA fragments (21%) appeared to be discriminative in this data set and were used for the genotypic conformity study.

The similarity matrices for the thus created AFLP markers were calculated by applying the most commonly used ‘Simple Matching’ (m/n), ‘Jaccard’ ($a/n-d$), and the ‘Dice’ ($2a/2a+b+c$) coefficients, respectively. (...) software (Applied Maths) was used to produce three similarity matrices. The Jaccard coefficient is the international standard for similarity calculations based on binary data. To visualise the relationship between samples a dendrogram was created.

WGS is a method for analysing variations between the complete DNA sequences of organism's genomes, including both coding (genes) and non-coding regions. The process generates massive amounts of data, which are then analysed using bioinformatics tools to assemble the genome and identify variations between different genomes. This complete sequence can then be used to identify variations such as single nucleotide polymorphisms (**SNPs**), insertions and deletions (**Indels**), and structural variations between different genomes. In this case sequencing generated 518.321.010 raw reads. After quality filtering this resulted in 750.035 SNPs for cluster analysis. (...) All chromosomes are represented by this filtered set of SNPs.

Cophenetic correlations per branch that were found *with the AFLP analysis* are shown in dendrograms in (figures 4a and 4b of) the NakTuinbouw report. Figure 4b and the accompanying text is reproduced below.

Figure 4b: Zooming in on the samples of the WGS analysis (Phase 2). The dendrogram is calculated based on the score of 94 polymorphic AFLP markers using the 'Jaccard' similarity coefficient and UPGMA analysis. Varieties are analyzed in duplo for the check on the reproducibility. Numbers correspond with the sample number in Table 1. Sub numbers correspond with two out of three selected DNA isolations. On the horizontal axis, the similarity is given. Branch quality is indicated in the dendrogram by the 'cophenetic values' given in percentages.



Regarding the AFLP results the report concludes:

“4.5 Conclusion AFLP analysis on the research question

Based on the AFLP profiles generated with four primer combinations, no differences were observed between the 'Cayene' strain and 'BR06' strain. Based on the AFLP data, the strains 'Cayene' and 'BR06' are genetically identical.”

The results of *the WGS analysis*, parts of Table 6 of the report, a matrix with the genetic similarities (in %) of the WGS samples based on 750,035 SNP markers (see above) is shown below. High similarities are shown in increasingly darker green and low similarities are in white.

Customer ID		Nakt_01	Nakt_02	Nakt_03	Nakt_04	Nakt_05	Nakt_07	Nakt_12	Nakt_15
	Strain	Heirloom-1	Heirloom-2	Heirloom-3	Brawn	Lambert 818	XXX	Cayene	BR06
Nakt_01	Heirloom-1	100,00							
Nakt_02	Heirloom-2	99,89	100,00						
Nakt_03	Heirloom-3	99,88	99,88	100,00					
Nakt_04	Brawn	85,85	85,86	85,85	100,00				
Nakt_05	Lambert 818	76,89	76,89	76,89	75,86	100,00			
Nakt_07	XXX	68,13	68,13	68,12	66,31	79,67	100,00		
Nakt_12	Cayene	99,88	99,88	99,88	85,86	76,89	68,13	100,00	
Nakt_15	BR06	99,89	99,89	99,89	85,86	76,89	68,12	99,89	100,00
Nakt_16	Tuscan 860	72,38	72,38	72,38	74,35	77,57	76,95	72,38	72,37
Nakt_17	Tuscan 820	75,56	75,56	75,55	79,36	75,20	69,15	75,56	75,56
Nakt_duplo_15	BR06	99,86	99,86	99,85	85,82	76,89	68,16	99,85	99,85
Nakt_duplo_12	Cayene	99,88	99,88	99,88	85,85	76,89	68,13	99,88	99,88

Regarding the WGS-analysis it is explained:

5.5 Observations based on WGS data

- Within the WGS analysis of 14 mushroom samples, 750.035 high-quality SNPs were identified.
- The genetic distances between the samples were calculated and visualized in a dendrogram.
- By the analysis of duplo samples, the average technical error rate could be determined. The average technical error rate is set at 0,116% with a standard deviation of 0,0235. The average genetic similarity between duplo samples is 99,88%.
- Based on scores of 750.035 SNPs the strains 'Cayene', 'Heirloom-1', 'Heirloom-2', 'Heirloom-3' and 'BR06' show extremely high genetic similarities. These genetic similarities (Table 7) are similar to the genetic similarities between duplo samples (Table 6 and 7).

5.6 Conclusion WGS analysis on the research question

Based on the score of 750.035 SNP markers generated in the WGS analysis, no differences exceeding the expected technical error rate were observed between strain 'Cayene' and strain 'BR06' (ATCC). Based on the WGS data, the strains 'Cayene' and strain 'BR06' are genetically identical.

The overall conclusion of this report is:

6 CONCLUSION ON THE RESEARCH QUESTION

To answer the research question, the AFLP analysis and the WGS analysis did not reveal any significant differences between the 'Cayene' strain and the 'BR06' (ATCC) strain. Based on these results we conclude that both strains are genetically identical.

- 2) An expert report of Prof. ██████████ dated 1 May 2024 on genetic similarity of certain mushroom strains. The report was prepared with the assistance of Dr. ██████████ of Verinomics. Under 'Results' the following is mentioned:

Of specific interest are the BR06/Heirloom identical test samples. These are Heirloom-1, Heirloom-2, Heirloom-3, both replicates of BR06 from the ATCC, and both replicates of ██████████ Cayene (Table 4). All of these samples had >99.8% similarity with the BR06/Heirloom reference panel samples (Table 2) as well as previously tested samples ITSP and ██████████ Cayene. As such, while BR06, Heirloom, ██████████ Cayene, and ITSP have different identifying codes, any measurement of genetic identity between them returns a value that is on par with biological replicates from the same strain. In other words, from a genetics perspective they are indistinguishable.

Part of Table 4 of this report with the title '*Similarity measurements for test samples vs BR06/Heirloom reference panel*' is reproduced below:

Strain ID	Replicate	BR06-1	BR06-2	BR06-3	BR06-4	BR06-5	HRLM-1	HRLM-2	HRLM-3
BR06	1	0.9992	0.9989	0.9989	0.9991	0.9991	0.9992	0.9990	0.9989
BR06	2	0.9989	0.9986	0.9986	0.9988	0.9988	0.9989	0.9986	0.9985
Heirloom-1	1	0.9992	0.9990	0.9989	0.9992	0.9992	0.9992	0.9990	0.9989
Heirloom-2	1	0.9992	0.9990	0.9989	0.9992	0.9992	0.9992	0.9990	0.9989
Heirloom-3	1	0.9991	0.9989	0.9988	0.9991	0.9991	0.9991	0.9989	0.9988
█████ Cayene	1	0.9992	0.9990	0.9989	0.9992	0.9992	0.9992	0.9990	0.9989
█████ Cayene	2	0.9993	0.9990	0.9990	0.9992	0.9992	0.9992	0.9990	0.9989
XXX	1	0.8241	0.8243	0.8245	0.8241	0.8241	0.8241	0.8242	0.8246
XXX	2	0.8241	0.8243	0.8245	0.8242	0.8241	0.8241	0.8243	0.8246
BR05 (Brawn)	1	0.9086	0.9083	0.9083	0.9085	0.9085	0.9086	0.9083	0.9082

The conclusion of this report is quoted below.

The primary sample of interest, the (...) Cayene strain (e.g. AM27S7 and AM27S11), was firmly established by the data as being genetically identical to Amycel’s patented mushroom strain BR06 (e.g. AM27S8 and AM27S23), and its commercially available equivalent, the Heirloom (e.g. AM27S1, AM27S2, AM27S3).

A commercial mushroom strain is the outcome of combining two homokaryons, each originating from the combination of random meiotic events and a distinct genetic background. To independently recreate even one of these homokaryons, much less the two required to independently create a heterokaryon strain such as BR06, would be virtually impossible. Consequently, I conclude that the only plausible explanation for the replicate-level sequence similarity between the strains BR06 and (...) Cayene identified in this report and independently in the Variety Tracer report is that the two strains are identical copies.

- 3) An expert report of Prof. ██████ of 1 May 2024, concerning a phenotypical comparison of the Cayene strain with the phenotypical characteristics of BR06 described in the patent. The report contains the following:

B. My Instructions

I have been asked to review Amycel’s European patent EP 1 993 350 B2 and provide my opinion on test results regarding yield, cap color, cap shape and compatibility for the Cayene strain compared

C. Executive Summary and Conclusions

8. Two Tests (Test I and Test II) were performed at the ANICC – Centre Technique, France. In Test I, data on yield, cap color and cap shape were collected. In Test II, additional yield data were collected to assess compatibility of the strains.

9. The results showed statistically the same (Test I) and significantly higher (Test II) yield for Cayene compared to Amycel 2400, and a statistically significant darker cap color and a statistically significant higher cap shape value for Cayene compared to Amycel 2400. The results further show that Cayene is incompatible with Amycel 2400.

10. Based on the discussed results, Cayene displays the same characteristics relative to Amycel 2400 as stated in the patent for BR06 relative to Amycel 2400.to the Amycel 2400 strain in view of this patent.

III. Conclusion

44. The discussed yield, cap color, cap shape and compatibility results regarding Cayene compared to Amycel 2400 are in line with what is described in patent EP 1 993 350 B2 for BR06 compared to Amycel 2400. My conclusion is that Cayene displays the same characteristics relative to Amycel 2400 as stated in the patent for BR06 relative to Amycel 2400.

20. In support of his defence that the Cayene strain does not infringe the patent, Defendant submitted the translation of an expert report of Assistant Professor Dr. ██████ ██████ that was also filed in the Polish proceedings in December 2023. She compared brown mushroom cultivars (fruit bodies) of the strains Cayene and Heirloom genetically, using two methods of analysis: an ITS analysis (starters ITS4 and ITS5; analysis 1) and an analysis of SNPs and Indels in the whole genome (analysis 2).

ITS analysis refers to the examination of Internal Transcribed Spacer (ITS) regions of the ribosomal RNA (rRNA) gene cluster of the strains. The ITS region is generally highly conservative.

In both analysis a sample of Cayene and a sample of Heirloom were analysed. The (English translation of) the report contains the following:

Analysis 1: Comparison of two brown mushroom cultivars within the ITS sequence.

(...)

Fresh mushroom fruit bodies (Photo 1) taken from:

A. Cayene - two locations (designation A1, A2).

B. Heirloom-three locations (designation B1, B2, B3)

(...)

Mushroom groups A and B differ in 10 items within the ITS area.

(...)

Conclusions

The differences within the analyzed genome segment (ITS) between the Cayene and Heirloom became the reason for conducting a whole genome study to search for SNPs and indels.

Analysis 2: Comparison of two brown mushroom cultivars regarding the presence of SNPs and indels in the whole genome.

(...)

4. Results

As a result of the sequencing, high-quality data were obtained, which allowed bioinformatics analysis.

The bioinformatics analysis resulted in 666 indels (Table1) and 57 SNPs (Table 2). The characteristic changes in the genome (indels, SNPs) found only in the Cayene and not found in the Heirloom and ARP23, are summarized in the table below.

(....)

5. Conclusions

As a result of the analysis, changes in the genome (SNPs, indels) were identified that were found only in the Cayene, and were not present in the Heirloom and ARP23. The discovered indels and SNPs can be used to identify strains.

21. Defendant also argues that the provisional measures should not be granted because of lack of urgency as Amycel waited unreasonably long in filing the application and/or because the patent is (likely to be) invalid. The invalidity grounds that the Defendant mentions are:

- The patent should not have been granted as it concerns subject matter excluded from patentability in Art. 53 (b) European Patent Convention (“EPC”)
- The patented mushroom strain lacks novelty over (a) the Hungarian strain Barnakalapu BKU-100 or █████ SP-B1 (= Cayene) and/or (b) AA-0096, the wild strain described in [0012] as basis for crossing with another strain to obtain BR06.

GROUNDS FOR THE ORDER

Competence

22. According to Art. 31 UPCA (which provides that international jurisdiction of the court is established in accordance with Brussels Regulation 1215/2012, as amended by EU Regulation 542/2014, “BR”), and Arts. 26, 35 and 71, 71a and 71b BR, this court is competent to hear the case regarding a European patent that is not opted out for the Contracting Member-States where the patent is valid. Competence for provisional measures follows from Art. 32 (1) (c) UPCA. This local division is undisputedly competent to hear the case as the alleged (threatened) infringement has occurred in The Netherlands (Art. 33 UPCA).

Inadmissible due to unreasonable delay?

23. The Defendant's argument that the Application for provisional measures be rejected because Amycel did not file the application with undue delay after it became aware of the alleged infringement (R. 211.4 RoP), is dismissed.
24. Unreasonable delay in starting the proceedings, and consequently possible lack of temporal urgency required for the ordering of provisional measures, only exists if the Applicant has behaved in such a negligent and hesitant manner in requesting provisional measures after it became aware of the infringement of the patent that, from an objective perspective, it must be concluded that the Applicant is not interested in promptly enforcing its rights. In such case it is not appropriate to allow it to claim provisional legal protection.¹
25. In assessing unreasonable delay, the court has to take into account that the burden of presentation and proof for facts allegedly establishing the entitlement to initiate proceedings and the infringement or imminent infringement of the patent, as well as for all other circumstances allegedly supporting the Applicant's request, lies with the Applicant.² This means that the Applicant will need to be able to submit reasonably necessary evidence to convince the court with a sufficient degree of certainty that the Applicant's right is being infringed or threatened with infringement. This requires appropriate preparation of the proceedings. The Applicant therefore only should apply to the court if it has reliable knowledge of all the facts that make legal action in the proceedings for provisional measures promising and if it can substantiate these facts. The Applicant may prepare for any possible procedural situation that may reasonably arise, based on the circumstances, in such a way that it can present the requested information and documents to the court and successfully rebut arguments reasonably to be expected from the Defendant's side. In view of the urgent nature of an action for provisional measures, there is generally no possibility for the Applicant to carry out (or have carried out) any necessary subsequent investigations or experiments during ongoing proceedings and to obtain the required documents after the objection by the Defendant is received. On the other hand, the Applicant must not delay proceedings unnecessarily. As soon as it has knowledge of the alleged infringement, it must investigate it, take the necessary measures to clarify it and obtain the evidence required to support its claims. In doing so, it must diligently initiate and complete the required steps at each stage in a timely fashion. As soon as the Applicant has all the knowledge and evidence that reliably enable a promising legal action, it must file the application for provisional measures without unreasonable delay.
26. It is not, or not substantially, in dispute that Amycel first became aware of the (imminent) patent infringement within UPC-territory, in The Netherlands, in late July 2023. Contrary to Defendant's assertion, Amycel's knowledge of allegedly infringing acts with the mushroom strain Cayene in Poland (since 2017 and as Defendant states even earlier under different names) is as a principle not relevant for the admissibility of this action before the UPC as Poland is not a Contracting Member State (CMS).
27. Amycel argues that it acted diligently to obtain evidence to substantiate infringement of the patent in the circumstances of this case. It explains the time that lapsed between the finding of the Cayene at the end of July 2023 in the Netherlands and the filing of the Application on 3

¹ cf LD Munich, Order of 19 September 2023 in UPC_CFI_2/2023 (ACT_459746/2023); LD Düsseldorf, Order of 9 April 2024 in UPC_CFI_452/2024 (ACT_589655/2023); LD Düsseldorf, Order of 30 April 2024 in UPC_CFI_463/2023 (ACT_590953/2023) and LD Hamburg, Order of 3 Juni 2024 in UPC_CFI_151/2024 (ACT_16267/2024)

² Order of the UPC Court of Appeal of 26 February 2024 in UPC_CoA_335/2023 (App_576355/2023), p. 27/28

May 2024 as follows. Firstly, it pointed out that Defendant in the Polish proceedings contests the infringement and the validity of the reports on the genetic identity of the Cayene strain and the BR06 strain submitted in those proceedings on the merits (hereinafter: the “Polish reports”). In particular, Defendant raised doubts about the starting materials used for these tests. Thus, Amycel decided not to rely on the Polish reports but to analyse the Cayene found in UPC territory separately for identity to the strain, BR06, which is the subject of claim 1 of the patent and additionally, to meet the criticism of Defendant regarding the Polish reports. Amycel selected NakTuinbouw to perform the genetic analysis. Such analysis is time consuming due to the following. As part of the preparations for the genetic testing, NakTuinbouw needed to collect – and await the arrival – of samples from the American Type Culture Collection (ATCC) needed for investigation (the strains AA-0096, BR06 and bridging strain 4x29) and samples from other (commercial) sources. Then, NakTuinbouw had to prepare those samples for DNA extraction. This involves the growing of mycelia colonies on plates to harvest sufficient mycelia for DNA isolation, which took considerable time. Following these steps, both AFLP analysis and WGS analysis (at third party GenomeScan) were performed. This data generation could be initiated end December 2023/start January 2024. The generated WGS data were then provided to Professor ██████████/Verinomics for analysis when they became available at the end of January 2024. The data were subsequently analysed, and reviewed, to prepare and finalize the extensive genetic reports from NakTuinbouw and Professor ██████████ filed in these proceedings.

28. Amycel explained that in parallel it tried to come to an out-of-court solution with the Defendant to prevent further proceedings. During these negotiations, the Defendant played for delay, according to Amycel, and raised several defences including, by letter of 22 November 2023, the defence that the Cayene is morphologically different:

“We also want to emphasize that there are morphological differences (e.g., cap color, flesh hardness) and physiological differences (e.g., nature of mycelial growth, response to growing conditions), as well as differences that have been shown in the in-depth analysis.”

On 15 December 2023 it became clear to Amycel that no settlement would be reached.

29. Because the morphological defence was brought up by Defendant during negotiations (as well as in the Polish proceedings), Amycel felt it had to be well prepared to address this in case Defendant would raise such a defence in these front-loaded provisional measures proceedings. This in spite of the fact that Amycel considers such data irrelevant to establish infringement. Amycel then looked for and found an independent third party (ANICC) that was able to start testing as of mid-January 2024. These tests – just like the genetic testing – took considerable time to perform and return results (very simply put it takes time to grow, harvest and collect data on mushrooms). The final raw data of these tests were provided at the end of March 2024, and subsequently analysed and reviewed by Professor ██████████ who finalized the report submitted in these proceedings by the end of April 2024. After securing all infringement data, Amycel then filed the Application without delay.
30. The Defendant did not really contest that it takes time to do genetic and morphological analysis with respect to mushroom strains. His arguments that Amycel could have used the Polish reports and that the morphological research was not necessary to establish infringement, do not hold. The court finds that Defendant himself gave rise to such additional analysis due to his earlier position, as explained above. Moreover, also in these proceedings, Defendant asserts that morphological and physiological characteristics of Cayene are relevant to the question of (no) infringement.
31. The court finds Amycel’s explanation of the timeline plausible. In the circumstances of this case, Amycel acted diligently as a prudent patentee to anticipate the defences raised by

Defendant pre-trial by performing both genetical and morphological experiments. The court also appreciates that it takes time to collect both genetical and morphological evidence, as explained by Amycel. As Amycel started proceedings as soon as it had gathered the reasonable evidence, there is no unreasonable delay.

Validity of the patent

32. The court is convinced with a sufficient degree of certainty (R. 211.2 RoP) that the patent is valid; Defendant's invalidity arguments are rejected.
33. Both novelty arguments raised by Defendant are unsubstantiated whereas the burden of presentation and proof for facts concerning the lack of validity of the patent and other circumstances allegedly supporting the Defendant's position lies with the Defendant.³ No genetical documentation was submitted to support the argument that the Hungarian strain Barnakalapu BKU-100, that was obtained in Hungary in 1991 and allegedly then deposited at a university in Poland, is identical to the mushroom strain, BR06 of claim 1 of the patent and was publicly available before the priority date. The same applies to the brown mushroom strain █████ SP-B1. Of the latter it has not been argued that it was available before the priority date (4 August 2005), as only documentation referencing this strain dated 2006 were submitted. Defendant's statement that there was no time to substantiate these novelty arguments as it only had two weeks, is not acceptable in view of the Polish proceedings and the pre-trial negotiations. The declaration of the Defendant and related persons that the strain Barnakalapu was brought from Hungary in 1991 and that the █████ SP-B1 strain is identical to this, and that the █████ SP-B1 strain was later re-named Cayene, appears unsupported by any concrete evidence to that effect and, hence, is insufficient to convince the court.
34. Also, the assertion that the AA-0096 strain (also referred to as ARP23) is identical to BR06, is unconvincing. Defendant's main support for this assertion is that tables 1, 4 and 6 of the patent show no marker differences between AA-0096 and BR06. According to the teaching of the patent, and as explained above, the wild mushroom strain AA-0096 is one of the parent strains of the strain, BR06, mentioned in claim 1 of the patent. That strain was crossed with the bridging cross strain 4x29 that was created by crossing the commercially available white mushroom hybrid strain (a U1 derivative) and the commercially available brown mushroom strain Amycel 2400. As explained in the patent, it was one of the objects of the invention to obtain a mushroom hybrid strain which contained some advantageous traits of the wild mushroom strain AA-0096 into commercial browns. Hence, the information contained in tables 1, 3, 6 of the patent are meant to illustrate that BR06 and AA-0096 share certain genetic fragments. The (genetic) differences between these two strains are however not shown. One cannot conclude from these data therefore that the strains are in fact the same. Also Dr. █████ analysis does not support this conclusion as she only shows similarities between the Heirloom and ARP23, but she did not look at the differences. She also does not conclude that AA-0096/ARP23 and BR06 (from which Heirloom is obtained) are the same. The novelty attacks are hence unsuccessful.
35. Defendant furthermore asserts that the patent's claim contravenes Art. 53(b) EPC, which pertains to the exclusion of "plant or animal varieties" from patentability. Defendant reasons that a mushroom strain should be equated to a plant variety and, therefore, extend to subject matter that is excluded from patentability. This is, according to Defendant, in line with the spirit of the UPOV convention, which allows for the registration of mushroom varieties.
36. Art. 53(b) EPC as an exception to patentability must be interpreted restrictively and the exception should be construed narrowly. This is a generally accepted rule of (patent) law, that

³ Order of the UPC Court of Appeal of 26 February 2024 in UPC_CoA_335/2023 (App_576355/2023), p. 28

was, for instance, mentioned specifically in the context of Art. 53 (b) EPC by the Enlarged Board of Appeal of the EPO in its decision of 25 March 2015 in case G2/12.⁴

37. The exclusion concerns plant and animal varieties only and therefore does not encompass organisms other than plants and animals, such as mushrooms which belong to the fungi kingdom that is taxonomically distinct from the plant and animal kingdoms. As Amycel points out, mushrooms were not simply 'forgotten' by the legislator when the EPC was drafted. Fungi were recognized as a separate kingdom, distinct from plants and animals, years before the EPC was signed and entered into force. Consequently, Defendant's assertion that back then the world was divided into animals, plants, and microbes (bacteria, etc.), is incorrect.
38. From the legislative process prior to the introduction of amendment of Rules 27 and 28 of the Implementing Regulations of the EPC⁵, it can be derived that fungi are not excluded from patentability. The Proposal CA/56/17 for new Rules 27(b) and 28(2) EPC of the President of the EPO dated 6 June 2017, contains the following in paragraph 64:

The proposed new paragraph 2 of Rule 28 EPC explicitly refers to Article 53(b) EPC and replicates the term "essentially biological process". It furthermore employs the terms "plants or animals", as in Article 53(b) EPC. This clarifies that plants and animals as well as propagation materials thereof are covered by the exclusion from patentability, but not any plant- or animal-derived products like fur or meal, or even other products like fungi or yeasts. (emphasis added)

39. In view of the above, the court concludes that mushroom varieties/strains are not excluded from patentability by art. 53(b) EPC. Consequently, this invalidity attack fails, and the patent is assumed to be valid.

Infringement

40. The court is convinced with a sufficient degree of certainty (R. 211.2 RoP) that the Applicant's right is infringed by the offer and distribution of the contested embodiments within the Contracting Member State of The Netherlands (Art. 25(a) UPCA).
41. Specifically asked about claim construction, both parties agree that in the context of these proceedings the patent should be interpreted in such a way that for infringement it is sufficient to establish that Cayene and the BR06 strain, mentioned in claim 1 of the patent, are *genetically* identical. However, they do not agree on what this means. Defendant argues that the patent is only infringed in case a genetic similarity of 100% can be established on the basis of the available evidence.
42. Amycel points out, however, that due to technical and biological reasons, it is inevitable that the sequencing even of identical samples, results in a measurement of not 100% identity but of 99,88% with a standard deviation of 0,0235. This follows from the reports of NakTuinbouw and Prof. ██████████ (see paragraph 19 above at 1) and 2)), wherein duplicates/replicates of the same strain, i.e. samples that would be assumed to be 100% identical such as two samples of BR06 or different Heirloom samples, do not show 100% identity with genetic analysis, but an identity of 99,85 – 99,89 % (see table 6 shown above). This is due to sequencing errors that are inevitable with DNA analysis. From the results obtained in the NakTuinbouw and ██████████ reports, the average technical error rate was determined by the analysis of duplicate samples. The average technical error rate was determined at 0,116% with a standard deviation of 0,0235. The average genetic similarity between duplicate samples of the same strain is 99,88%.

⁴ Tomatoes II, reasons point VII.2(3), p.41-43

⁵ Decision of the Administrative Council of 29 June 2017 amending Rules 27 and 28 of the Implementing Regulations of the European Patent Convention OJ EPO 2017, A56

43. The court finds Amycel's argument convincing. Given the parties agreement on claim interpretation, with which the court finds no reason to disagree in the context of the present summary proceedings, the claim of the patent should be construed in such a way that for infringement genetic identity to the strain mentioned in the claim (BR06), is required, as also Defendant argues. However, genetical identity can be assumed to exist also in case the sequencing results show a similarity of 99,88 % or above (with a standard deviation of +/- 0,0235). In fact, in view of the inevitable sequencing errors 100% identity will likely not be found even between identical samples (i.e. samples for the same strain) with the present techniques.
44. The results presented in the NakTuinbouw and ██████████ reports (see paragraph 19 above at 1) and 2)), show a similarity between Cayene and BR06 and Cayene and Heirloom samples, that falls within the threshold established for identical samples, such as between two Heirloom or two BR06 samples. The same results were obtained by two different sequencing methods (AFLP and WGS) and by two different computational approaches. In view of this, the court is sufficiently certain that based on the evidence filed by the Applicant Cayene and the Heirloom/BR06 can be considered so genetically similar that this is indistinguishable from genetical identity within the applicable limits of experimental error.
45. Defendant submitted a report by Dr. ██████████ to support his point of view that Cayene and Heirloom are genetically distinct (see paragraph 20 above). Dr. ██████████ reports 723 genetic variations (666 indels and 57 SNPs) between the Cayene and the Heirloom strains. Her report does not contain any interpretation of the results, nor does it conclude that the strains are genetically identical (or different) by any standard. As Prof. ██████████ pointed out, the number of variations found by Dr. ██████████ (723) is a number of variations that is within what is to be expected between biological replicates (identical clones) due to sequencing errors rather than to actual genetic sequence differences. As a result, the whole genome sequencing data filed by Dr. ██████████ (analysis 2) actually supports the conclusions from the NakTuinbouw and ██████████ reports.
46. Dr. ██████████ confirmed at the hearing that sequencing errors exist, that she was only able to sequence one sample of each strain and that she was unable to apply filtering criteria. Furthermore, upon request, she told the court that her analysis was based on 102,178 SNP markers in total. This would mean that the number of variations in SNP's between Cayene and Heirloom ($57:102,178=0,0558\%$ so 99,9442% identity) falls well within the range for identical samples established by NakTuinbouw and ██████████
47. Taking this into account, all results show that Cayene and BR06 are, when subjected to sequencing, found to have genetic identity at least to the same degree as would be expected for biological replicates of the same strain. Hence, the court considers it on the balance of probabilities to be more likely than not that (claim 1 of) the patent is infringed with the sale or offering Cayene spawn. In view of the parties' position on claim interpretation, the court will not consider the morphological data, even if the court is sufficiently convinced by the ██████████ report that Cayene has the same characteristics as described in the patent as important and attributed there to strain BR06.
48. If Defendant's arguments are to be understood to include a prior use argument, this is denied. Prior use is a territorial right and is not sufficiently substantiated, let alone for UPC-territory.

Requested orders and weighing of the interest of the parties

49. The result of the above is that the injunction requested sub A (see paragraph 1 above) is granted as it is considered necessary to stop further infringement, and thus has factual urgency. The balancing of interest of the parties does not lead to a different result, also taking into

account what was considered above regarding the temporal urgency. The infringement is ongoing and Amycel thus has a legitimate interest to stop such (imminent) infringement and did not act with unreasonable delay in requesting the measures. The fact that the number of established infringing acts is limited (see paragraphs 14 and 15 above) is, other than Defendant argued, not a reason to tilt the balance of interest in his favour.

50. The injunction will be limited to the strain Cayene for which it was established that it infringes. No other infringing products have been alleged. The additional requests sub B (delivery up of products) and sub C (information on distribution) will also be granted in so far as reasonable and appropriate (also in terms of temporal urgency) as provisional measures (R. 211.1 and Art. 8 Enforcement Directive⁶). Defendant did not object to these additional measures in case infringement is established. To avoid execution issues, a time limit is attached to the order for the delivery up of products. The injunction and additional requests shall be granted for the UPC Member States where the patent is valid, as requested (Art. 34 UPCA).

(Interim award of) costs, value of the case, date of R.213.1 RoP, security, enforceability

51. Defendant as the losing party is obliged to bear the costs of the proceedings in accordance with Article 69 UPCA. The court will decide this in principle in these proceedings, analogously applying R. 118.5 RoP. A cost decision (including the height of the costs to be reimbursed) is to be taken in the proceedings on the merits, that will have to follow these proceedings. The court shall specify the date pursuant to R. 213.1 RoP relevant for starting these proceedings in the order.

52. Amycel has asked the court to order Defendant to pay an interim award of costs pursuant to R. 211.1 (d) RoP by way of a separate application (App_39185/2024). Specifically, it seeks an interim award of costs for reimbursement of the following amounts:

- costs of representation up to the ceiling for recoverable representation of EUR 56,000. - based on a case value of EUR 500,000.00 (adding that the actual representation costs substantially exceed the ceiling)
- other costs: costs of experts and
- court fees of EUR 11,000.00

It submitted several exhibits to substantiate the costs, namely specification of work performed by the representatives, invoices of experts, while requesting to keep the information regarding work performed by the representatives and the expert costs confidential to the public in line with R. 262.2 RoP.

53. Defendant was given the opportunity to comment in writing to the application for an interim award of costs, which he did. He does not object to the granting of an interim award of costs as such, but only to the height of the amount requested. Firstly, he does not agree that the value of the dispute is EUR 500,000.00 as Amycel has argued. According to Defendant, Amycel has set the value this high only to raise the ceiling for recoverable costs. The value should be much lower in view of limited sales in UPC-territory; Poland is the main market for Defendant. In the Polish proceedings the value was set at about EUR 60,000.00. Also, it contests that the expert reports, and hence the costs related thereto, were necessary.

⁶ Directive 2004/48/EC of the European parliament and of the council of 29 April 2004 on the enforcement of intellectual property rights

54. It is at the discretion of the court to order the requested interim award of costs as provisional measure. In this case the court finds it reasonable to grant such award because the Defendant did not object to such award and given the procedural behaviour of Defendant.
55. However, as in this case proceedings on the merits will have to follow shortly, and the costs can thus be recovered in the (cost proceedings following) this action, the amount awarded will be substantially lowered as compared to the amount requested. Amycel has not argued that there are financial reasons (on either side) for granting an interim award of costs. The interim amount to be awarded will thus be limited to the court fees incurred in these proceedings (EUR 11,000.00). The other costs, notably those involved with the expert and costs of representation, are also relevant for the proceedings on the merits and are to be recovered there.
56. The court will limit the value of the proceedings relevant for determining the ceiling for recoverable costs of representation, as it agrees with Defendant that a case value of EUR 500,000.00 is not sufficiently substantiated. As Defendant is requesting EUR 200,000.00 as security (R. 211.5 RoP, see next paragraph), the court assumes that this amount reflects the potential damage the Defendant expects from (enforcing) an injunction. The court finds it reasonable to set the value of the case at that amount. The case value set in the Polish infringement case, is, without further explanation, not considered relevant for determining the value of the proceedings before the UPC.
57. The request of the Defendant pursuant to Rule 211.5 RoP to make the granting of provisional measures dependent on the provision of a security by Amycel for the enforcement of EUR 200,000.00 is granted because Amycel did not object to this.
58. The immediate enforceability of the orders follows from Rules 350 (2), 354 (1) RoP. According to these rules, the orders made here, except for the order regarding the (final) costs but including the interim award of costs, are directly enforceable in each Contracting Member State from the day of their service, in this case subject to the deposit of the security specified above.





ORDER

Having heard the parties, the court by way of provisional measures:

1. Orders Defendant by way of preliminary injunction to refrain from direct infringement of European patent EP 1 993 350 B2 in the territories of The Netherlands, Germany, France and Italy, with immediate effect after service of this order, by making, offering and / or placing on the market the brown mushroom strain Cayene as specified in the complaint, or importing or storing this strain for those purposes in accordance with the claim of the patent (Articles 63(1) and 25(a) UPCA);
2. Orders the Defendant to pay to the court a penalty payment (which may be repeated) of up to EUR 50,000.00 for each day or part of a day that the aforementioned injunction is not complied with; the penalties will be determined by this Local Division of the court upon request by Amycel (Article 63(2) UPCA; and R.354.3 RoP);
3. Orders Defendant to deliver up, within one week after the service of this order, the brown mushroom strain Cayene infringing EP 1 993 350 B2 present in the territories of The

Netherlands, Germany, France and Italy, so as to prevent their entry into or movement within the channels of commerce (R. 211(1)(b) RoP);

4. Orders Defendant to provide, within two weeks after the service of this order, to Amycel (c/o its representatives) a written account with the full names and address details of all customers to whom the Defendant offered for sale, sold and/or delivered or otherwise traded in the Cayene strain within the territories of The Netherlands, Germany, France and Italy (R. 211 (1) RoP);
5. Orders Defendant to pay to the court a penalty payment (which may be repeated) of up to EUR 5,000.00 for each day or part of a day that the aforementioned injunction at 4. is not complied with; the penalties will be determined by this Local Division of the court upon request by Amycel (Article 63(2) UPCA; and R.354.3 RoP).
6. Orders the Defendant to pay to Amycel an interim award of costs in the sum of EUR 11,000.00 (R. 211.1(d) RoP).
7. The above is immediately enforceable but for Amycel only once it has provided security in favour of the Defendant in the form of a deposit in the amount of EUR 200,000.00 (two hundred thousand Euro) on the bank account of the UPC dedicated thereto or a bank guarantee of a respected bank established in a Contracting Member State.
8. Rejects the claims in all other respects.
9. Determines that the Defendant shall bear the costs of the proceedings.
10. Sets the date as referred to in R. 213.1 RoP at 30 calendar days after service of this order.
11. Sets the value of the dispute at EUR 200,000.00.

Edger Brinkman	<p>Edger Frank BRINKMAN</p>  <p>Digitally signed by Edger Frank BRINKMAN Date: 2024.07.31 00:56:22 +02'00'</p>
Rute Lopes	<p>Rute Alexandra Da Silva Sabino Lopes</p>  <p>Assinado de forma digital por Rute Alexandra Da Silva Sabino Lopes Dados: 2024.07.30 12:52:25 +01'00'</p>
Steen Wadskov-Hansen	<p>Steen Lyders Lerche Wadskov-Hansen</p>  <p>Digitalt signeret af Steen Lyders Lerche Wadskov-Hansen Dato: 2024.07.30 13:20:48 +02'00'</p>
Margot Kokke	<p>Margot Elsa KOKKE</p>  <p>Digitally signed by Margot Elsa KOKKE Date: 2024.07.30 17:16:06 +07'00'</p>
On behalf to the registry	 <p>Digitally signed by Silke Fest Date: 2024.07.30 12:51:05 +02'00'</p>

INFORMATION ABOUT APPEAL

An appeal to this order may be brought in accordance with Art. 73 (2) (a) UPCA and R. 220.1 (c) and 224.1(b) RoP within 15 calendar days of the service of this order.

INFORMATION ON ENFORCEMENT (ART. 82 UPCA, ART. 37(2) STATUTE, R. 118.8, 158.2, 354, 355.4 RoP)

An authentic copy of the enforceable order will be issued by the Deputy Registrar upon request of the enforcing party (R. 69 Rules governing the Registry of the Unified Patent Court) taking into account the security to be deposited.

ORDER DETAILS

Order number: ORD_44133/2024
Action No.: ACT_23163/2024
UPC number: UPC_CFI_195/2024
Application Type: Application for provisional measures