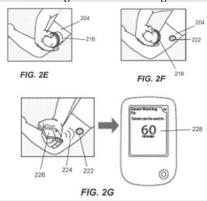
UPC CFI, Local Division The Hague, 19 June 2024, Abbott v Sibio – EP879

Suspensive effect in appeal insofar as the order extends to Ireland: <u>IPPT20240819</u>, <u>UPC CoA</u>, <u>Sibio</u> v Abbott

continuous glucose monitoring device



PATENT LAW - PROCEDURAL LAW

Immediately enforceable preliminary injunction for direct infringement and order to deliver up any devices in direct or indirect possession, subject to a recurring penalty payment (Rule 211 RoP)

International jurisdiction UPC (Article 31 UPCA)

- Competence for Ireland undisputed (Article 26 BR),
- <u>Court does not understand the application to also</u> involve the UK

In this case (unlike the parallel case 14945/2024), Sibio c.s. did not challenge the competence of this court with respect to Ireland. According to Art. 31 UPCA (which provides that the international competence of the court is established in accordance with Brussels Regulation 1215/2012 as amended by EU Regulation 542/2014, "BR"), and Art. 26, 35 and 71, 71a and 71b BR, this court therefore is competent to hear the case. Incidentally, Art. 24 BR does not apply as no invalidity defence has been raised. Since the UK is no longer a Contracting Member State, the court does not understand the application to also involve the UK. This local division is undisputedly competent to hear the case as the alleged (threatened) infringement occurred (inter alia) in the Netherlands (Art. 33 UPCA).

Abbott's interests outweigh any interest of Sibio (<u>Rule 211(3) RoP</u>); action not devoid of purpose (<u>Rule 360 RoP</u>)

• Given Sibio c.s.' breaches of their cease-anddesist declarations, which do not include an irrevocable penalty payment in case of breaches. According to their submissions, Sibio c.s. has left the markets where the patent is in force. This court therefore fails to see any legitimate interest on their part in opposing the preliminary injunction sought.

Source: **Unified Patent Court**

UPC Court of First Instance,

Local Division The Hague, 19 June 2024

(Brinkman, Rinkinen, Kokke)

UPC_CFI_130/2024

ACT_14944/2024

Order

of the Court of First Instance of the Unified Patent Court Local Division The Hague

delivered on 19/06/2024

concerning provisional measures

HEADNOTE:

Sufficient interest in this case despite unilateral ceaseand-desist declaration (yes). Application is not devoid of purpose (<u>R. 360 RoP</u>). Competence for Ireland not contested.

KEYWORDS:

provisional measures; cease-and-desist declaration; legitimate interest; competence

REFERENCE CODE ECLI: Not provided

CLAIMANT

1) Abbott Diabetes Care Inc.

(Applicant) - 1360 South Loop Road - CA 94502 - Alameda - US

Represented by Eelco Bergsma

DEFENDANTS

1) Sibio Technology Limited

(Defendant) - 6/F., Manulife Place, 348 Kwun Tong Road - - - Kowloon - HK

Represented by Thomas Gniadek

2) Umedwings Netherlands B.V.

(Defendant) - Treubstraat 1 - 2288 EG - Rijswijk - NL Represented by Thomas Gniadek

PATENT AT ISSUE

Patent no. Proprietor

EP2713879 Abbott Diabetes Care Inc.

COMPOSITION OF PANEL – FULL PANEL

Presiding judge and judge-rapporteur Edger Brinkman Legally qualified judge Petri Rinkinen

Legally qualified judge Margot Kokke

LANGUAGE OF PROCEEDINGS: English SUBJECT-MATTER OF THE PROCEEDINGS

Application for a preliminary injunction and other provisional measures filed on 20 March 2024 (<u>R. 206</u> Rules of Procedure (RoP)).

FACTS

The facts presented below are mostly based on the application as they were not opposed by the Defendants.

The patent

The Applicant (hereinafter also referred to as "Abbott") is the proprietor of European patent number EP 2 713 8791¹ (the "patent") which contains the following independent claim 1 and dependent claim 4:

https://worldwide.espacenet.com/patent/search/family/047891854/publication/EP2713879B1?q=pn%3DEP2713879B1

¹ To be found in the EPO Espacenet register at:

1. An apparatus comprising:

a first assembly including a portion of an on-body device;

a second assembly coupleable to the first assembly to form the on-body device and comprising a sharp supporting a sensor of the on-body device;

an applicator assembly releasably coupled to the first assembly; and

a container releasably coupled to the second assembly, wherein in response to force applied to the applicator assembly along a longitudinal axis (Z) that drives the applicator assembly into the container, the applicator assembly releases and retrieves the second assembly from the container and couples

the first assembly to the second assembly to form the onbody device releasably held within the applicator assembly, and wherein the on-body device once held within the applicator assembly is ready to be applied

4. The apparatus of any one of the preceding claims wherein:

the first assembly is an electronics assembly including sensor electronics and an enclosure surrounding the sensor electronics, the sensor electronics including a processor and a communications facility; and wherein the second assembly is a sensor assembly including a sensor, a sharp supporting the sensor, a support structure, and

a connector coupled to the sensor and coupleable to the sensor electronics, the support structure supporting the connector and sensor, and releasably supporting the sharp; or

the second assembly is an electronics assembly including sensor electronics and an enclosure surrounding the sensor electronics, the sensor electronics including a processor and a communications facility; and wherein the first assembly is a sensor assembly including a sensor, a sharp supporting the sensor, a support structure, and a connector coupled to the sensor and coupleable to the sensor electronics, the support structure supporting the connector and sensor, and releasably supporting the sharp.

The application for the patent was filed on 11 December 2012 and has an earliest priority date of 11 December 2011. The application was published on 9 April 2014 and the notice of grant of the patent was published on 26 July 2017. The patent is valid and in force in Germany, France, The Netherlands and Ireland, which are Contracting Member States of the UPCA (the Agreement on a Unified Patent Court). The patent was opted out of the competence of the UPC, but this opt-out was withdrawn by Abbott on 14 March 2024.

Market situation

Abbott has been a developer, manufacturer and marketer of continuous glucose monitoring ("CGM") devices since 2007. Its series of devices is called FreeStyle Libre. Since 2014, these devices have comprised an applicator (i.e. an insertion device), an on-body unit consisting of an analyte sensor (for glucose) and sensor electronics as an integrated unit, and a display device

(such as a reader or smartphone) with proprietary software. According to Abbott, this technology utilizes the invention disclosed in the patent. Abbott is the main supplier of CGM products in the Contracting Member States. In Europe, Abbott serves over 1.3 million patients with its FreeStyle Libre products and has a market share of approximately 80%.

Defendant 1 ("Sibio") also manufactures CGM systems. Since 2021, Sibio has been marketing a CGM device in China. Recently, at the end of 2023, Sibio entered the European market with its CGM device, called GS1. Defendant 2 ("Umedwings" and together with Sibio "Sibio c.s." or the "Defendants") is named in the documentation for the GS1 device as an EU importer.

SUBMISSIONS

A Chinese company, Shenzhen Sibionics Co. Ltd, filed a Protective Letter concerning the patent on 29 September 2023. In the protective letter, the company argued that it (or a member of the group) would not infringe the patent by providing the GS1 devices in the Contracting Member States. It is the understanding of this Court that Shenzhen Sibionics Co. and Sibio Technology Limited (Defendant 1) belong to the same group of companies.

Abbott lodged the Application for a preliminary injunction and other provisional measures on 20 March 2024 at the UPC Local Division The Hague. The applicant was provided with the aforementioned Protective Letter and decided not to withdraw its application (R.207.8 and R. 209.5 RoP).

As per the instructions of the Judge-Rapporteur, the Defendants lodged an Objection to the application for provisional measures on 23 April 2024.

Again, as instructed by the Judge-Rapporteur, on 8 May 2024 Abbott lodged a Reply to the Objection to the application for provisional measures.

The Defendants lodged a Rejoinder to this Reply on 15 May 2024, as stipulated by the Judge Rapporteur.

An oral hearing was held in the matter on 22 May 2024 at the Local Division of The Hague.

The hearing was recorded and Abbott submitted the notes of their pleading.

The following attorneys attended the oral hearing of 22 May 2024:

On behalf of Abbott

Wim Maas (Taylor Wessing, lawyer)

Eelco Bergsma (Taylor Wessing, lawyer)

David Mulder (Taylor Wessing, lawyer)

Faziel Abdul (Taylor Wessing, lawyer)

Iris van der Heijdt (Taylor Wessing, lawyer)

Peter Haartsen (AOMB - patent attorney)

Raimond Haan (AOMB – patent attorney)

On behalf of Sibio c.s.

Dr Thomas Gniadek, Simmons & Simmons LLP

Dr Fritz Lahrtz, Simmons & Simmons LLP

Oscar Lamme, Simmons & Simmons LLP

Diptanil Debbarma, Simmons & Simmons LLP

ORDER SOUGHT

Abbott contends that its patent is valid and that both independent claim 1 and dependent claim 4 are (threatened to be) infringed by the Defendants, among

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others through the offering for sale of the GS1 Devices on Sibio's website sibionicsshop.com, which is targeted at Europe.

It therefore requests that the Court, for the Contracting Member States in which the patent is in force:

- (a) grant a preliminary injunction for direct infringement of the patent by prohibiting the Defendants, individually and jointly, from infringing the patent in any way, with immediate effect after service of the order to be rendered in this matter, in particular by making, offering and / or placing on the market the GS1 Device, or importing or storing the GS1 Device for those purposes (Articles 63(1) and 25(a) of the UPCA);
- (b) order the Defendants to provide counsel for Abbott, within 4 weeks after service of the order rendered in this matter, with a written statement, substantiated with appropriate documentation of:
- (i) the origin and distribution channels of GS1 Devices in the Contracting Member States in which the patent is in force (including the full names and addresses of the legal entities that are involved).
- (ii) the quantities delivered, received or ordered, as well as the price obtained for GS1 Devices in the Contracting Member States in which the Patent is in force; and
- (iii) the identity of any third party involved in the production or distribution of GS1 Devices in the Contracting Member States in which the patent is in force (including the full names and addresses of the legal entities that are involved).

(<u>Article 62(1)</u> and <u>67 of the UPCA</u>; and <u>R. 211</u> Rules of Procedure)

- (c) order the Defendants to deliver up to a bailiff appointed by Abbott, at their own expense, or alternatively orders the seizure, of any GS1 Device in stock and / or otherwise held, owned or in the direct or indirect possession of the Defendants in the Contracting Member States in which the patent is in force, within 1 week after service of the order to be rendered in this matter, and to provide counsel for Abbott with proper evidence of the full and timely compliance with this order within 10 days after the delivery up to the bailiff or seizure (Article 62(3) of the UPCA; and R. 211.1 Rules of Procedure);
- (d) order the Defendants to comply with the orders under 1.1(a) 1.1(c) above, subject to a recurring penalty payment of up to EUR 250,000.00 or another amount as the Court may order, to the Court for each violation of, or non-compliance with, the order(s), plus up to EUR 100,000.00 for each day, or part of a day counting as an entire day, that the violation or non-compliance continues, or another amount as determined by this Court in the proper administration of justice (Article 63(2) of the UPCA; and R. 354.3 Rules of Procedure); (e) append an order for the enforcement to its decision,
- (e) append an order for the enforcement to its decision, while declaring that the order is immediately enforceable (Article 82(1) of the UPCA);
- (f) order the Defendants to jointly and severally bear reasonable and proportionate legal costs and other expenses incurred by Abbott in these proceedings and orders, insofar such costs are to be determined in separate proceedings for the determination of such costs,

that the Defendants pay to Abbott by means of an interim award of costs of the sum of EUR 11,000.00 or another amount as the Court may order (<u>Article 69</u> of the UPCA; and <u>R. 118.5</u> and <u>150.2</u> Rules of Procedure).

Abbott also requests that the amount of security, if any, be fixed separately for each enforceable part of the Court's decision.

DEFENCE

In their Objection, Sibio c.s. did not rely on the defence presented in the protective letter, nor did they challenge the validity of the patent or the alleged infringement. They also did not dispute the urgency of the application or the competence of the court. Instead, the Defendants provided a unilateral cease-and-desist declaration with certain undertakings concerning the withdrawal of the GS1 device from the market in Germany, France and The Netherlands. In response to criticism from Abbott, Sibio c.s. amended their cease-and-desist declaration on 15 May 2024. Sibio c.s. argue that the application has therefore become devoid of purpose and that there is no longer any need to adjudicate on it, and hence it should be disposed of by way of an order under **R. 360 RoP**.

Sibio c.s. further request that the court impose on Abbott the obligation to pay for the fees and costs incurred since Abbott did not send any warning letter before initiating these proceedings and hence unnecessary costs were incurred.

GROUNDS FOR THE ORDER

Competence for Ireland

Abbott's application in section 7.2 sets out the following: "The Patent is valid and in force in the Contracting Member States of Germany, France, The Netherlands and also Ireland. It is also in force in the UK.". Read together with the order sought, this entails that Abbott apparently wishes the order to also cover Ireland, which is a signatory state to the UPCA, and therefore a Contracting Member State, even though Ireland has not yet ratified the Agreement. In this case (unlike the parallel case 14945/2024), Sibio c.s. did not challenge the competence of this court with respect to Ireland. According to Art. 31 UPCA (which provides that the international competence of the court is established in accordance with Brussels Regulation 1215/2012 as amended by EU Regulation 542/2014, "BR"), and Art. 26, 35 and 71, 71a and 71b BR, this court therefore is competent to hear the case. Incidentally, Art. 24 BR does not apply as no invalidity defence has been raised. Since the UK is no longer a Contracting Member State, the court does not understand the application to also involve the UK. This local division is undisputedly competent to hear the case as the alleged (threatened) infringement occurred (inter alia) in the Netherlands (Art. 33 UPCA).

Requirements of R. 211 RoP

Abbott does not accept Sibio's unilateral cease-and-desist declaration. Furthermore, Abbott has sufficiently demonstrated that Sibio c.s. did not fully comply with their own unilateral declaration to cease and desist. Firstly, even though their declaration was rendered on 23 April 2024, Abbott undisputedly was able to place an order for a GS1 device on 29 April 2024 in both

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Germany and the Netherlands. Delivery of the device was made on 3 and 4 May 2024, respectively. Secondly, after Sibio c.s. was made aware of this and, according to their submissions, had "reorganized its sales activities", Abbott was still able to purchase another GS1 device on 17 May 2024 through the website sibionicsshop.com, where the GS1 device was still offered in Dutch to the Dutch public. This was not disputed by Sibio c.s.

Given Sibio c.s.' breaches of their cease-and-desist declarations, it is understandable that Abbott considers that it cannot properly rely on Sibio c.s.' undertakings. As pointed out by Abbott, the declarations do not include an irrevocable penalty payment in case of breaches. Indeed, the only commitment is that the amount of the penalty is left to be determined by Abbott and to be reviewed by this Local Division. This would require Abbott to initiate new proceedings before this court instead of simply executing the order sought.

On the other hand, according to their submissions, Sibio c.s. has left the markets where the patent is in force. This court therefore fails to see any legitimate interest on their part in opposing the preliminary injunction sought. Abbott's interests therefore outweigh any interests of Sibio c.s.

In the written phase of this application for provisional measures, Sibio c.s. did not contest Abbott's position that it had acted promptly. It was not until the oral hearing that Sibio c.s. remarked that the GS1 had been known to Abbott since October 2023, and therefore, Abbott had taken half a year to bring these proceedings. Sibio c.s. however did not take the position in this case that any such delay was unreasonable. The remark, even if intended to dispute Abbott's promptness, was neither substantiated nor does it contradict Abbott's submission in the application (at 11.4) and Annex E1. Therefore, this argument is to be rejected as inconclusive and lacking substance.

It should also be taken into consideration that this remark was made, if not too late then at least inexcusably late. Prior to the hearing and given the extensive written discussion in this case with only minor legal issues at stake, the Judge-Rapporteur suggested to the parties that only 10 minutes of pleading time be allocated to each side with no possibility of rebuttals. Neither party opposed this. On this basis, making remarks at the oral hearing (after Abbott had already pleaded), without actually drawing the legal conclusion that Abbott acted with unreasonable delay and without any explanation as to why they did not bring this forward much earlier (as they extensively did in the parallel case), constitutes an inexcusable delay late and contravenes the principles of a fair trial.

Consequently, all conditions set out in **R. 211 RoP** are deemed to be met regarding a preliminary injunction.

Thus, contrary to what Sibio c.s. argue, the court does not consider the action to be devoid of purpose; there is still a need to adjudicate it.

Order specifics

The order sought is to be partly allowed. The application sub (a) for an injunction will be limited to the GS1 device at issue. No threat of infringement by another

device was asserted (or could be established) at this time. Application sub (b) is to be denied as the court fails to see sufficient interest in it within these preliminary measure proceedings, given that either Abbott is already sufficiently aware of the information requested or that the declaration as rendered already provides for it (as this was part of Sibio c.s.' unilateral undertaking) and no breach of this part of the undertaking has been asserted. Application sub (c) will be allowed. The penalty as requested sub (d) will be ordered, in amended form as follows.

Sibio c.s. did not request the court to provide security for enforcement of any order in this action. The court ex officio also sees no need to order security for enforcement (R. 211.5 RoP). No damages can be envisaged resulting from enforcement of the preliminary injunction, given that the defendants are largely absent from the markets where the patent is in force and that Sibio c.s.' unilateral cease-and-desist declaration is still in place. No argument was made specifically in relation to Ireland.

Regarding the costs, Sibio c.s. are considered the losing party and hence required to bear the costs in accordance with **Article 69 UPCA**. Insofar as Sibio c.s. have relied on Article 69.3 UPCA, this is to be denied. Given that this court deems it appropriate to order a preliminary injunction, it cannot be stated that the costs were incurred unnecessarily. Insofar as Sibio c.s. relies on the absence of a warning letter, this cannot be held to be sufficient grounds to rule otherwise, especially given that these proceedings were allegedly anticipated by Sibio c.s. in view of their filing of a protective letter regarding this patent (on the basis of arguments on which they ultimately did not rely). The interim award as requested for EUR 11,000.00 will be granted, these costs being the same as the court fee (R. 211.1d RoP). A date for commencement of the 31 calendar days/20 working days time period as envisaged in R. 213 RoP will be set. Since Abbott did not request (nor give reasons) to set a later date, the court will specify 30 days after service to allow for - in case the order is not enforced immediately (R. 354.1 RoP) – some extra time for the parties to come to a settlement to avoid costs for initiating proceedings on the merits.

ORDER

The court:

(a) grants a preliminary injunction for direct infringement of European patent EP2713879, prohibiting the Defendants, individually and jointly, from infringing this patent, with immediate effect after service of this order, by making, offering and / or placing on the market the GS1 Device, or importing or storing the GS1 Device for those purposes in accordance with claim 1 or 4 of European patent EP2713879 in Germany, France, The Netherlands and Ireland (Articles 63(1) and 25(a) UPCA);

(b) orders the Defendants to deliver up to a bailiff appointed by Abbott, at their own expense, any GS1 Device in stock and/or otherwise held, owned, or in the direct or indirect possession of the Defendants in France, The Netherlands, Germany and Ireland, within one week

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after service of this order, and to provide Abbott's counsel with proper evidence of the full and timely compliance with this order within 10 days after the delivery to the bailiff; (<u>Article 62(3) UPCA</u>; and <u>R. 211.1 RoP</u>);

- (c) orders the Defendants to comply with the orders (a) and (b) above, subject to a recurring penalty payment of up to EUR 10,000.00 for each violation of, or noncompliance with, the order(s), or up to EUR 100,000.00 for each day, or part of a day counting as an entire day, that the violation or non-compliance continues. These penalties will be determined by this Local Division of the court upon request by Abbott (Article 63(2) UPCA; and R 354.3 RoP);
- (d) declares that this order is immediately enforceable (Article 82(1) UPCA);
- (e) orders the Defendants to jointly and severally bear reasonable and proportionate legal costs and other expenses incurred by Abbott in these proceedings, up to the applicable ceiling, and orders, that the Defendants pay to Abbott an interim award of costs in the sum of EUR 11,000.00 (R. 211.1(d) RoP);
- (f) specifies the date as referred to in <u>R. 213 RoP</u> at 30 calendar days after service of this order;
- (g) rejects the claims in all other respects.

INFORMATION ABOUT APPEAL

An appeal to this order may be brought in accordance with <u>Art. 73 UPCA</u> and R. 220.1 RoP within 15 calendar days of the notification 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 decision or 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).

E.F. Brinkman Presiding judge M. Kokke Legally qualified judge P. Rinkinen Legally qualified judge Employee of the Registry

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