

**ORDER**  
**of the Court of First Instance of the Unified Patent Court**  
**issued on 8 October 2026**  
**concerning EP 2 753 187 B2 (R. 211 RoP provisional measures)**

Claimant

1. **CAELUS LIFESCIENCES IP B.V.**  
Thijsseweg 11  
2629 JA Delft  
The Netherlands  
("Caelus")

Represented by D.F. de Lange,  
B.B. van der Wansem and R.  
Rijkema

Defendants

1. **PENDULUM THERAPEUTICS INC.**  
933 20th St.  
94107 San Francisco, California  
United States of America  
("Pendulum")
3. **IHERB NETHERLANDS B.V.**  
Schiphol Boulevard 359  
1118 BJ Schiphol  
The Netherlands  
("iHerb")

Represented by S.M.M.  
Versaevel and W.J.G. Maas

Represented by S.M.M.  
Versaevel and W.J.G. Maas

PATENT AT ISSUE

*Patent no.*

*Proprietor/s*

**EP 2 753 187 B2**

Caelus Lifesciences IP B.V. and Stichting Amsterdam UMC

DECIDING JUDGE

Single judge  
(all parties consented)

**Edger Brinkman**

LANGUAGE OF PROCEEDINGS: English

## SUBJECT-MATTER OF THE PROCEEDINGS: Provisional measures (R. 211 RoP)

### PROCEDURE

1. The following submissions are before the Court:
  - Application for provisional measures of 11 May 2026, with exhibits C01-C34;
  - Objection by Defendant 1 of 20 July 2026, with exhibits WT001-WT029;
  - Objection by Defendant 3 of 20 July 2026, with exhibits WT001-WT027;
  - Notice of 22 July 2026 that the case was withdrawn against Defendants 2 and 4-5;
  - Reply to the validity defence of 5 August 2026, with exhibits C35-C40.
- 1.1. The oral hearing took place on 27 August 2026. Both sides submitted pleading notes.

### SUMMARY OF FACTS

2. **The application is based on the following facts:**
  - 2.1. *The parties and the products*
    - 2.1.1. Applicant Caelus Lifesciences IP B.V. is, together with Stichting Amsterdam UMC, proprietor of European patent EP 2 753 187 B2. The patent protects the use of the bacterium *Eubacterium hallii*, (hereinafter also *E. hallii* or *hallii*) in preventing and/or treating insulin resistance and/or insulin resistance-related complications.
    - 2.1.2. Defendant 1, Pendulum Therapeutics Inc., is a San Francisco-based microbiome company that manufactures and markets microbiome-based probiotic products for metabolic health, including Pendulum Glucose Control and Pendulum Metabolic Daily.
    - 2.1.3. Defendant 3, iHerb Netherlands B.V., is established in the Netherlands and is identified by Pendulum on its website as a retailer of Pendulum products.
  - 2.2. *The patent*
    - 2.2.1. The patent is entitled “*Method for preventing and/or treating insulin resistance*”. It was filed on 30 August 2012 based on international application WO 2013/032328 and claims priority from US 201161528931 and NL 2007319, both dated 30 August 2011. The patent was granted on 24 October 2018 and, after opposition and appeal proceedings before the EPO, was maintained in amended form. The B2 specification was published on 6 August 2025. The patent is in force in the UPC Contracting Member States Belgium, Denmark, Germany, France, Italy, the Netherlands and

Sweden and also in Switzerland. The patent was opted out of the exclusive competence of this Court until 11 May 2026 when the opt-out was withdrawn.

2.2.2. The patent contains the following claim 1:

*Eubacterium hallii* and/or *Alcaligenes faecalis* for use in preventing and/or treating insulin resistance and/or insulin resistance-related complications selected from metabolic syndrome, dyslipidemia, type 2 diabetes mellitus, and insulin resistance in endocrine diseases such as in obese subjects with type 1 diabetes mellitus, Cushing's disease and lipodystrophy syndromes.

2.2.3. Claim 1 of the patent concerns *Eubacterium hallii* and/or *Alcaligenes faecalis* for use in preventing and/or treating insulin resistance and/or insulin resistance-related complications selected from metabolic syndrome, dyslipidemia, type 2 diabetes mellitus, and insulin resistance in endocrine diseases. The asserted claims include claims 1, 2, 4, 5, 7, 11, 12, 13 and 14. For brevity of this order, the Court refers to the online version of the patent to be found at: <https://data.epo.org/publication-server/pdf-document?pn=2753187&ki=B2&cc=EP&pd=20250806>

2.3. *Technical background*

**Glucose metabolism and insulin resistance**

2.3.1. The patent relates to the use of specific gut bacteria, in particular *hallii* and/or *A. faecalis*, for the prevention and/or treatment of insulin resistance and related metabolic complications, including metabolic syndrome, dyslipidemia, and type 2 diabetes mellitus.

2.3.2. Glucose metabolism refers to the processes by which glucose is absorbed, distributed, used and stored, and how blood glucose levels are regulated in the fed and fasting state. Glucose is an important compound in the human body, it i.a. serves as a major fuel for cellular respiration. The body aims to maintain blood glucose concentrations at a steady state level within a narrow physiological range (homeostasis).

2.3.3. The hormone 'insulin' is a central regulator of glucose metabolism. It promotes glucose uptake and utilization in insulin-sensitive tissues (notably muscle and fat tissue) and suppresses glucose output by the liver (hepatic endogenous glucose production, "EGP"). Together, these effects help lower blood glucose concentrations, returning to the normal physiological range.

2.3.4. Insulin sensitivity refers to how effectively body cells respond to insulin to take up glucose, with high sensitivity indicating efficient metabolism. Insulin sensitivity can be divided into (1) hepatic insulin sensitivity (i.e. insulin's ability to suppress endogenous glucose production) and (2) peripheral insulin sensitivity (i.e. insulin's ability to stimulate glucose disposal in peripheral tissues). In metabolic research, hepatic and peripheral insulin sensitivity are commonly discussed in terms of suppression of EGP and the rate of glucose disposal ("Rd"). See e.g. par. [0003] and [0016] of the Patent.

- 2.3.5. Low insulin sensitivity, or insulin resistance, refers to a physiological condition in which the body's cells in insulin-sensitive tissues respond less effectively to insulin, resulting in insulin becoming less effective at lowering blood sugars. Consequently, the pancreas often needs to produce more insulin to keep blood glucose in the normal ranges. If this compensation becomes insufficient, blood glucose levels can rise outside the normal range and cause adverse health effects, like type 2 diabetes mellitus.

### **Bacteria**

- 2.3.6. *E. hallii* is a member of the Bacteria Kingdom. In biology, all living organisms are classified as belonging to certain groups based on shared characteristics. The science of naming, defining and classifying living organisms is called 'taxonomy'.
- 2.3.7. In taxonomy, organisms with shared characteristics are grouped together into so-called taxa. Different individual taxa can be aggregated to form together a supergroup of higher rank, thus creating a taxonomic hierarchy. In simplified terms these ranks include Domain, Kingdom, Phylum, Class, Order, Family, Genus and Species.
- 2.3.8. In relation to bacteria, the term "strain" is widely used to refer to a low-level taxonomic rank within a given species. "Strain" refers to the descendants of a single isolate or common ancestor that share certain identifying characteristics. In other words, the term is commonly used in the art to further distinguish groups within the same species.

### **The role of gut microbiota in metabolic disease**

- 2.3.9. The human intestine contains a dense and diverse community of micro-organisms, including over a thousand different bacterial species (par. [0002] of the Patent). Humans therefore live in a form of symbiosis with their gut bacteria. These bacteria help process food components that human enzymes do not fully digest, produce signalling metabolites (such as butyric acid) that can act locally in the intestine and systemically elsewhere in the body, and interact continuously with the intestinal wall and immune system.
- 2.3.10. In humans, altered colonic microbiota have been correlated to obesity, but consensus regarding specific bacterial groups of species and evidence for a causative role was lacking. This was particularly true for the small intestinal microbiota, which is relatively inaccessible but exposed to a large surface area (par. [0005] of the Patent). The Patent has changed this by identifying *hallii* and *A. faecalis* as the relevant bacterial species functionally involved in glucose metabolism in the small intestine (see further par. 43 below).
- 2.3.11. In addition, gut-derived hormones that are upregulated by *hallii*, through the production of i.a. butyrate, also play an important role in glucose metabolism. One

well-known example is GLP-1 (glucagon-like peptide-1), an intestinal hormone that helps the body release insulin after meals and supports blood glucose regulation. The GLP-1 hormone became a household name because of the breakthrough of GLP-1 receptor agonists such as Ozempic®.

### ***hallii* - taxonomical development, and *Anaerobutyricum soehngenii***

- 2.3.12. *hallii* is an anaerobic bacterium found in the human intestinal tract. *hallii* is a relatively fast-growing anaerobe with the metabolic capacity to convert lactate into butyrate (par. [0017] of the Patent). According to par. [0003] of the Patent, short chain fatty acids such as butyrate produced by specific gut bacteria could serve as a signal that directly influences host hepatic and peripheral insulin sensitivity.
- 2.3.13. The scientific taxonomy of bacteria is not static. In the literature, *hallii* was first referred to as *Eubacterium hallii* (*E. hallii*). In 2018 (four years after the priority date of the Patent), *hallii* was reclassified as *Anaerobutyricum hallii* (*A. hallii*).
- 2.3.14. The reclassification of *hallii* is described in the publication of Shetty et al. from 2018. In the abstract they write that *hallii* was misclassified as *E. hallii* and they propose that *hallii* be reclassified as the type strain of a novel genus *Anaerobutyricum*:

#### **Abstract**

A bacterial strain designated L2-7<sup>T</sup>, phylogenetically related to *Eubacterium hallii* DSM 3353<sup>T</sup>, was previously isolated from infant faeces. The complete genome of strain L2-7<sup>T</sup> contains eight copies of the 16S rRNA gene with only 98.0–98.5% similarity to the 16S rRNA gene of the previously described type strain *E. hallii*. The next closest validly described species is *Anaerostipes hadrus* DSM 3319<sup>T</sup> (90.7% 16S rRNA gene similarity). A polyphasic taxonomic approach showed strain L2-7<sup>T</sup> to be a novel species, related to type strain *E. hallii* DSM 3353<sup>T</sup>. The experimentally observed DNA–DNA hybridization value between strain L2-7<sup>T</sup> and *E. hallii* DSM 3353<sup>T</sup> was 26.25%, close to that calculated from the genomes (34.3%). The G+C content of the chromosomal DNA of strain L2-7<sup>T</sup> was 38.6 mol%. The major fatty acids were C<sub>16:0</sub>, C<sub>16:1 cis9</sub> and a component with summed feature 10 (C<sub>18:1</sub>C11/t9/t6c). Strain L2-7<sup>T</sup> had higher amounts of C<sub>16:0</sub> (30.6%) compared to *E. hallii* DSM 3353<sup>T</sup> (19.5%) and its membrane contained phosphatidylglycerol and phosphatidylethanolamine, which were not detected in *E. hallii* DSM 3353<sup>T</sup>. Furthermore, 16S rRNA gene phylogenetic analysis advocates that *E. hallii* DSM 3353<sup>T</sup> is misclassified, and its reclassification as a member of the family Lachnospiraceae is necessary. Using a polyphasic approach, we propose that *E. hallii* (=DSM 3353<sup>T</sup>=ATCC 27751<sup>T</sup>) be reclassified as the type strain of a novel genus *Anaerobutyricum* sp. nov., comb. nov. and we propose that strain L2-7<sup>T</sup> should be classified as a novel species, *Anaerobutyricum soehngenii* sp. nov. The type strain is L2-7<sup>T</sup> (=DSM 17630<sup>T</sup>=KCTC 15707<sup>T</sup>).

- 2.3.15. This proposal was followed in the field. Thus, currently *hallii* is taxonomically classified as follows:

|          |                                                          |
|----------|----------------------------------------------------------|
| Domain:  | Bacteria                                                 |
| Kingdom: | Bacteria                                                 |
| Phylum:  | Bacillota                                                |
| Class:   | Clostridia                                               |
| Order:   | Lachnospirales                                           |
| Family:  | Lachnospiraceae                                          |
| Genus:   | <i>Anaerobutyricum</i> (previously: <i>Eubacterium</i> ) |
| Species: | <i>hallii</i>                                            |

2.3.16. In the same publication, Shetty et al., the authors also propose that *E. hallii* strain L2-7 be classified as a novel species, namely *Anaerobutyricum soehngenii*, which proposal was followed. Again, as with switch from *E. hallii* to *A. hallii*, the renaming of a strain of *E. hallii* as a separate species called *A. soehngenii* therefore merely reflects a taxonomic reclassification and refinement, after publication of the Patent. At the relevant date of the Patent, the bacterium now known as *A. soehngenii*, was known as *E. hallii* (as was *A. hallii*).

2.3.17. The patent explains that the human intestine contains a dense and diverse community of micro-organisms and that specific gut bacteria, including *Eubacterium hallii*, may influence insulin sensitivity through short-chain fatty acids such as butyrate.

#### 2.4. *Description of the Patent*

2.4.1. The Patent explains that “*obesity is primarily a consequence of detrimental nutritional and physical habits against an unfavourable genetic background*” and that it “*is a major risk factor for the development of common medical conditions*”, such as type 2 diabetes mellitus. It further describes that the human intestine contains “*a dense and diverse community of micro-organisms*”, with a growing body of evidence for the role of intestinal microbiota in host metabolism (par. [0002]).

2.4.2. The Patent further explains that obese phenotypes are associated with altered gut microbiota, including reduced microbial diversity. It was presumed that the short-chain fatty acids acetate, propionate and butyrate could serve as a signal that directly influences host hepatic and peripheral and insulin sensitivity (pars. [0003][0005]).

2.4.3. In humans, altered colonic microbiota had been correlated with obesity at the priority date. There was, however, no consensus on specific bacterial groups and no clear causal evidence, particularly for the small intestine. Because metabolically healthy and unhealthy obese phenotypes differ mainly by the presence of insulin resistance, the Patent concludes that “*there is a need in the art to find further medicaments suitable to treat and/or prevent insulin resistance and/or type 2 diabetes mellitus*”. Preferably medicaments that can be easily incorporated into the patient’s lifestyle, for example in a food composition for daily consumption (par. [0005]).

2.4.4. The Patent defines insulin resistance in par. [0009] as “*a physiological condition where the natural hormone insulin, becomes less effective at lowering blood sugars*”. The resulting increase in blood glucose “*may raise levels outside the normal range and cause adverse health effects*”, such as type 2 diabetes mellitus.

2.4.5. Against this background, the inventors describe that they have found a causal role of the small intestinal microbiota in insulin resistance and dyslipidemia. In a landmark clinical study, 18 male subjects with newly diagnosed metabolic syndrome underwent small intestine biopsies. They were then randomised to receive either

allogenic fecal transplantation from a healthy lean donor or autologous fecal transplantation, i.e. their own fecal material (par. [0015], [0036]).

- 2.4.6. According to the description, six weeks after treatment subjects in the allogenic group showed a marked improvement in peripheral insulin sensitivity, while no significant changes were observed in the autologous group. A trend towards improved hepatic insulin sensitivity was also seen (par. [0048]-[0049]).
- 2.4.7. Analysis also showed that there was an increased abundance related to the bacterial taxa *hallii* and *A. faecalis* in the allogenic group, while in the autologous group *hallii* was almost two-fold reduced [par. [0017]]. Crucially, the inventors identified a significant association between *hallii* concentrations and the improvement in insulin sensitivity in humans (par. [0052], Table 1).
- 2.4.8. Example 3 concerns a mouse model. The Patent describes that short-term oral supplementation with *hallii* to the small intestine led to “*normalization of insulin resistance*” and improved fasting lipid profiles in these diabetic mice (pars. [0054]-[0055]).

### RELIEF SOUGHT

#### **3. The provisional measures sought are as follows**

##### **3.1. Caelus requests that the Court, by directly enforceable decision, order:**

- an injunction against Defendants 1 and 3 to refrain from infringing EP 2 753 187 B2 in any way, in particular by making, offering, placing on the market, using, importing or storing products containing *Eubacterium hallii* and/or *Alcaligenes faecalis* for use in the prevention or treatment of insulin resistance and/or related complications, including Glucose Control and Metabolic Daily, in Belgium, Denmark, Germany, France, Italy, the Netherlands, Sweden and Switzerland;  
and/or using and/or importing or storing for those purposes the Glucose Control and Metabolic Daily as specified in this Application and any other infringing strains, in the territories of Belgium, Denmark, Germany, France, Italy, the Netherlands, Sweden and Switzerland (art. 62(1) UPCA and R. 211(1)(a) RoP);
- delivery up of products suspected of infringing EP 2 753 187 B2 to prevent their entry into or movement within the channels of commerce in the relevant territories (Art. 62(3) UPCA, R. 211(1)(b) RoP);
- Defendants 1 and 3, within two weeks after service of the decision to be rendered in these proceedings, to provide to Caelus (p/a Brinkhof N.V.) a written account with information on:
  - (1) the origin and distribution channels of Glucose Control and Metabolic Daily, or any other product that falls within the scope of protection of EP 2 753 187 B2, within the territories of Belgium, Denmark, Germany, France, Italy, the Netherlands, Sweden and Switzerland (Art. 67(1)a UPCA);
  - (2) quantities produced, manufactured, delivered, received or ordered of Glucose Control and Metabolic Daily, or any other product that falls within the scope of protection of EP 2 753 187 B2, intended for the sale, supply or distribution within the territories of Belgium, Denmark, Germany, France, Italy, the Netherlands, Sweden and Switzerland (Art. 67(1)b UPCA);
  - (3) the identity, including full names and address details, of distributors, resellers,

retailers and other legal entities involved in the sale, supply or distribution of Glucose Control and Metabolic Daily, or any other product that falls within the scope of protection of EP 2 753 187 B2, within the territories of Belgium, Denmark, Germany, France, Italy, the Netherlands, Sweden and Switzerland (Art. 67(1)c UPCA);

- Defendants 1 and 3, at their own expense and within one week after service of the decision, to publish the operative part of the decision, or such other text as the Court deems appropriate, in English or respective local languages, without any additions or commentary, and to keep such publication available and clearly visible for a period of two months on the homepages of their respective websites (Art. 80 UPCA):  
(1) <https://pendulumlife.com/>  
(2) the country-specific domains of [iherb.com](https://iherb.com/), of the UPC and EPC member states where the Patent is in force;  
(4) <https://www.spectrumsupplements.eu/>; and  
(5) <https://naturesfix.co.uk/>.
- Defendants 1 and 3 to pay an interim award of Caelus' costs, immediately payable, of € 112.000,-, based on the ceiling for recoverable costs of a case with a value of € 750.000,- (R. 211(1)(d) RoP);
- Defendants 1 and 3 to pay the Court a penalty payment of € 50,000,-- 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 € 50,000,-- for each day or part of a day that the to be granted order under C and/or D. are not complied with in full (Art. 62(1) UPCA, R. 354(3) RoP).

## GROUNDS

### 4. **The grounds for the order are as follows**

#### 4.1. *Summary*

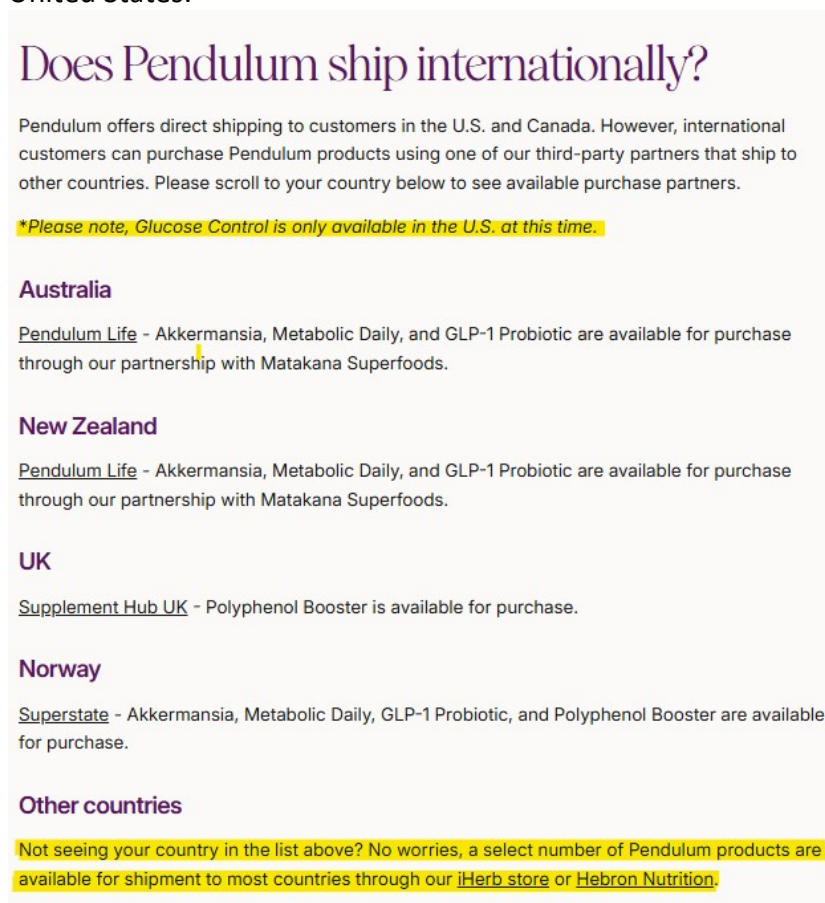
- 4.1.1. The proceedings concern a request for a provisional injunction and other measures based on alleged infringement of the patent. The Court finds below that it has jurisdiction and is competent to hear the case. The application was also made in a timely manner and meets other urgency requirements. The assessment of the alleged infringement and the alleged invalidity of the patent, if raised as a defence, depends inter alia on claim construction. Claim construction will be addressed together with the patent's teaching and the definition of the skilled person. The Court will conclude, addressing the invalidity defences and concerning infringement, that it is more likely than not that the patent will be considered valid and infringed. The objective urgency and proportionality of the requested measures are discussed in the last part.

#### 4.2. *Jurisdiction and competence*

- 4.2.1. The patent is a European patent and the initial opt-out was withdrawn. Accordingly, this Court has competence to hear actions for actual or threatened infringement of the patent within UPC territory. Internal competence of the Local Division The Hague follows because the application alleges actual or threatened infringement in the Netherlands and one of the defendants is domiciled in the Netherlands.

## Pendulum

- 4.2.2. Regarding Pendulum Therapeutics Inc., which is domiciled in the United States, jurisdiction is established because the alleged harmful event occurs or may occur in the Netherlands and the UPCA territory more generally. Glucose Control is in fact offered and sold by multiple Pendulum Retailers in the UPC/EPC territory. While for competence/jurisdiction, the Court should look more superficially at the allegedly infringing acts, to avoid repetition the Court will set out here that – assuming the products involved are held to be infringing a valid patent – Pendulum may be deemed an infringer, and there is a sufficient threat of infringement by it within the UPCA territory, in as far as designated, as well as Switzerland.
- 4.2.3. On its website, Pendulum facilitates international shipping and expressly identifies the companies iHerb and Hebron as official retailers of the Products outside the United States:



The screenshot shows a webpage titled "Does Pendulum ship internationally?". The text states that Pendulum offers direct shipping to the U.S. and Canada, but international customers can purchase products through third-party partners. A yellow highlight notes that "Glucose Control is only available in the U.S. at this time." Below this, there are sections for Australia, New Zealand, UK, and Norway, each listing available products. A final yellow highlight states that products are available for shipment to most countries through iHerb or Hebron Nutrition.

**Does Pendulum ship internationally?**

Pendulum offers direct shipping to customers in the U.S. and Canada. However, international customers can purchase Pendulum products using one of our third-party partners that ship to other countries. Please scroll to your country below to see available purchase partners.

*\*Please note, Glucose Control is only available in the U.S. at this time.*

**Australia**

Pendulum Life - Akkermansia, Metabolic Daily, and GLP-1 Probiotic are available for purchase through our partnership with Matakana Superfoods.

**New Zealand**

Pendulum Life - Akkermansia, Metabolic Daily, and GLP-1 Probiotic are available for purchase through our partnership with Matakana Superfoods.

**UK**

Supplement Hub UK - Polyphenol Booster is available for purchase.

**Norway**

Superstate - Akkermansia, Metabolic Daily, GLP-1 Probiotic, and Polyphenol Booster are available for purchase.

**Other countries**

*Not seeing your country in the list above? No worries, a select number of Pendulum products are available for shipment to most countries through our iHerb store or Hebron Nutrition.*

Caelus has successfully ordered multiple samples of Glucose Control and these were delivered in the UPC territory (the Netherlands) through Hebron Nutrition and in Switzerland (EPC territory) through iHerb, as will be discussed below. By directly linking interested parties to a website where they can place an order, Pendulum is offering the attacked products within the UPCA territory as well as Switzerland. Also, such subsequent sales are attributable to Pendulum if not as instigator, then at least as an accomplice to the offers and sales.<sup>1</sup>

<sup>1</sup> UPC CoA 3 October 2025, Philips v Belkin and UPC CoA 30 March 2026 (UPC\_CoA\_899/2025), Sinocare & Menarini/Abbott

4.2.4. Furthermore, and in particular regarding Switzerland, the claims against Pendulum and iHerb Netherlands (as will be explained below) concern the same patent, while one of the attacked products, Metabolic Daily, is the same and the same alleged infringing commercialisation into the relevant territories. There is a threat therefore of irreconcilable decisions.<sup>2</sup> iHerb Netherlands may be deemed a so-called “anchor defendant” in this scenario, for which the LD The Hague is the court of domicile. The UPC, and this Local Division, therefore has competence to hear the claims against Pendulum regarding Switzerland. The Court does not find that this case is initiated against either defendant solely to draw it off its court of domicile.

iHerb Netherlands B.V.

4.2.5. As regards iHerb Netherlands B.V., this Court has international jurisdiction because iHerb is domiciled in the Netherlands. The Court’s jurisdiction may also extend to the Swiss designation of the European patent in relation to iHerb, as requested. As will be discussed in more detail below, iHerb appears sufficiently involved in the offers on the website iherb.com, through which Caelus made a test purchase in Switzerland to at the very least assume a threat of infringement. Again, while for competence/jurisdiction, the Court should look more superficially at the allegedly infringing acts, to avoid repetition the Court will set out here that – assuming the products involved are held to be infringing a valid patent – iHerb may be deemed an infringer, and there is a sufficient threat of infringement by it within the UPCA territory, in as far as designated, as well as Switzerland.

4.2.6.



The Court reasons as follows. Caelus relies on sales in Switzerland via ch.iherb.com, the Swiss website. The Terms of Use on the Swiss website (“Nutzungsbedingungen”) explicitly refer to iHerb Netherlands B.V. and iHerb LLC as one entity: “(zusammenfassend „iHerb“, „wir“ oder „uns“):

Willkommen auf den Webseiten der iHerb-Familie, wozu unsere länderspezifischen Webseiten, mobile Webseiten, mobile Apps, Blogs und Webseiten für Prämien, Anreize und andere Werbeprogramme, wie das iHerb-Prämienprogramm, das iHerb-Affiliate-Programm und das Spar-Abo-Programm gehören (zusammenfassend die „Website“). Diese Nutzungsbedingungen von iHerb („Nutzungsbedingungen“) legen die Vereinbarung zwischen iHerb, LLC. („iHerb“), den Partnerunternehmen von iHerb wie iHerb Netherlands B.V., ein Unternehmen, das unter die Gesetzgebung der Niederlande fällt und deren Zentrale unter folgender Adresse zu finden ist: Schiphol Boulevard 359, 1118 BJ, Amsterdam Schiphol, Niederlande, registriert von der Handelskammer Amsterdam unter der Nummer 67635059; (zusammenfassend „iHerb“, „wir“ oder „uns“) und jedem Benutzer („Benutzer“, „Ihr“ oder „Sie“) dar. Diese Vereinbarung regelt Ihre Nutzung der Website, des iHerb-Prämienprogramms („Prämienprogramm“), des iHerb-Spar-Abo-Programms („Spar-Abo“) und der iHerb-Datenschutzbestimmungen („Datenschutzbestimmungen“). Bitte lesen Sie sich die Nutzungsbedingungen aufmerksam und vollständig durch, bevor Sie die Website nutzen, am Prämienprogramm oder am Spar-Abo teilnehmen, oder persönliche Informationen offenlegen.

<sup>2</sup> UPC CoA 2 July 2026, UPC-CoA-19/2026 (Guardant v Sophia)

Translation:

Welcome to the iHerb family of websites, which includes our country-specific websites, mobile websites, mobile apps, blogs, and websites for rewards, incentives, and other promotional programs, such as the iHerb Rewards Program, the iHerb Affiliate Program, and the Savings Subscription Program (collectively, the "Website"). These iHerb Terms of Use ("Terms of Use") set forth the agreement between iHerb, LLC ("iHerb"), iHerb's affiliates such as iHerb Netherlands B.V., a company governed by the laws of the Netherlands and headquartered at the following address: Schiphol Boulevard 359, 1118 BJ, Amsterdam Schiphol, Netherlands, registered with the Amsterdam Chamber of Commerce under number 67635059; (collectively, "iHerb," "we," or "us") and each user ("User," "your," or "you"). This Agreement governs your use of the Website, the iHerb Rewards Program ("Rewards Program"), the iHerb Savings Subscription Program ("Savings Subscription"), and the iHerb Privacy Policy ("Privacy Policy"). Please read the Terms of Use carefully and in their entirety before using the Website, participating in the Rewards Program or the Savings Subscription, or disclosing any personal information.

The same is true for the website's Privacy Policy:

iHerb, LLC. und seine Tochtergesellschaften, darunter iHerb Netherlands B.V. (zusammenfassend „iHerb“), respektieren Ihre Bedenken über den Datenschutz. Diese Datenschutzerklärung beschreibt die Arten an personenbezogenen Daten, die wir über Einzelpersonen durch unsere Website und mobilen Apps (zusammenfassend die „Services“) sammeln, wie wir diese Daten verwenden können, mit wem wir diese teilen können und die verfügbaren Optionen bezüglich unserer Verwendung der Daten. Die Datenschutzerklärung beschreibt außerdem die Maßnahmen, die wir ergreifen, um die personenbezogenen Daten zu sichern, wie lange wir diese behalten und wie Einzelpersonen uns bezüglich der Datenschutzpraktiken kontaktieren und ihre Rechte ausüben können.

Translation:

iHerb, LLC. and its subsidiaries, including iHerb Netherlands B.V. (collectively, "iHerb"), respect your privacy concerns. This Privacy Policy describes the types of personal information we collect about individuals through our website and mobile apps (collectively, the "Services"), how we may use that information, with whom we may share it, and the options available regarding our use of the information. The Privacy Policy also describes the measures we take to secure personal information, how long we retain it, and how individuals can contact us regarding our privacy practices and exercise their rights.

[REDACTED]

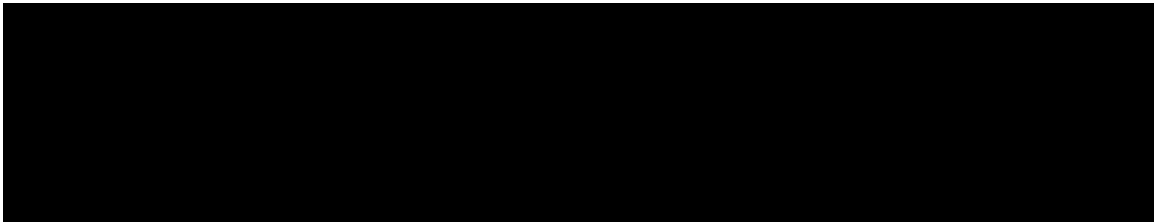
By the same reasoning, iHerb Netherlands B.V. is to be considered as a contracting party as well. And at the very least, iHerb Netherlands may be assumed to be an accomplice to the offers and sales through not only the Swiss but also the other UPCA country-specific websites of iHerb.com, and/or threaten to be so.

#### 4.3. *No undue delay*

- 4.3.1. Caelus has made it sufficiently clear that it acted without undue delay after recently becoming aware of the alleged infringement. However, defendants argue that Caelus should have discovered the infringement earlier. That argument is unfounded. It equates the mere availability of a product somewhere on the (online) market with actual or constructive knowledge of an infringement of the Patent. The UPC case law does not impose such a general obligation to monitor the market. This is also

confirmed in the recent case by the UPC CoA Paris in *Sophia Genetics/Guardant Health*<sup>3</sup>.

4.3.2.



4.3.3. Defendants also rely on the alleged availability of Metabolic Daily in Europe from 2023 onwards. The fact that a product may have been available through a third-party channel does not mean that the patent proprietor knew, or ought to have known, of that availability. As indicated above, there is no obligation to constantly monitor every party on every market.

4.3.4. The relevant trigger was therefore on 12 March 2026 when Caelus by its own admission became aware of the alleged infringement.<sup>4</sup> Defendants do not dispute that then Caelus acted without undue delay. The time taken to investigate the offers, obtain samples and secure independent verification was reasonable.

#### 4.4. *Skilled person*

4.4.1. The skilled person is a person or team with expertise in microbiology, probiotic formulation and metabolic disease, including knowledge of gut microbiota, insulin resistance and the development of bacterial compositions for nutritional or therapeutic use.

#### 4.5. *Claim construction*

4.5.1. The construction of the claims is in dispute between the parties. The principles applicable to claim construction have been set out by the UPC Court of Appeal in its final order in UPC\_CoA\_335/2023 (26 February 2024, NanoString v 10x Genomics, as rectified; see also CoA UPC\_CoA\_1/2024, 13 May 2024, VusionGroup v Hanshow; UPC\_CoA\_768/2024, 30 April 2025, Insulet v. EOFlow). A patent claim is not only the starting point but the decisive basis for determining the protective scope of a European patent under Art. 69 EPC in conjunction with the Protocol on the Interpretation of Art. 69 EPC. The interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. Rather the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim. A patent claim must always be interpreted from the perspective of a person skilled in the art. The skilled person interprets the features of a claim always in the light of the claims as a whole (UPC\_CoA\_1/2024, 13 May 2024, VusionGroup v Hanshow; UPC\_CoA\_768/2024, 30 April 2025, Insulet v EOFlow, UPC\_CoA\_646/2024, 25 November 2025,

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<sup>3</sup> Ibid.

<sup>4</sup> Exhibit C33, Correspondence between Mr Ferrara (Sales Manager at Sacco) and Mr Seegers (Caelus), regarding Pendulum's interest in purchasing the *A. soehngenii*.

Meril v Edwards). These principles for interpreting a patent claim apply both to the question of patent infringement and to the question of validity (NanoString v 10x Genomics, u.a., see also as to validity: Enlarged Board of Appeal, 18 June 2025, G1/2024). The Court will interpret the claims in light of the claim language, the description and the drawings, and from the perspective of the skilled person at the effective (priority) date (see specifically, UPC\_CoA\_646/2024, 25 November 2025, Meril v Edwards, para 64, last sentence).

4.5.2. Claim 1 may be divided into the following claim features:

- 1.1 *Eubacterium hallii* and/or *Alcaligenes faecalis*
- 1.2 for use in preventing and/or treating
- 1.2.a insulin resistance
- 1.2.b and/or insulin resistance-related complications selected from metabolic syndrome, dyslipidemia, type 2 diabetes mellitus, and insulin resistance in endocrine diseases such as in obese subjects with type 1 diabetes mellitus, Cushing's disease and lipodystrophy syndromes.

4.5.3. The other claims Caelus asserts further define the claimed composition and its form. Claim 2 concerns the incorporation of the bacteria in a food, feed or pharmacological composition; independent claim 4 specifies a pharmaceutical, food, or feed composition with *hallii* and/or *Alcaligenes faecalis* according to the use of claim 1, claim 5 specifies that the composition comprises *Eubacterium hallii*; and claim 7 further limits the composition to a food, food composition or food supplement. Claims 11 and 12 concern the dosage form of the composition, with claim 11 specifying a solid dosage form and claim 12 specifying that the solid dosage form may be a capsule, tablet or powder. Claim 13 specifies that the *Eubacterium hallii* is lyophilized, and claim 14 defines the quantity of bacteria present in the composition, namely between about  $10^6$  and about  $10^{12}$  bacteria.

#### *E. hallii*

4.5.4. According to the Defendants, claim 1 should be limited to one specific strain called L2-7 (or DSM 17630), later named *A. soehngenii*. They rely on Example 3, in which this strain L2-7 was used. However, Caelus rightly points out that an otherwise broader claim should not be limited to a particular strain used in an example. As a general rule, examples are not limiting and the claims recite *E. hallii*, without limitation. See e.g. the Paris Central Division in *Kinexon/Ballinno*<sup>5</sup>.

4.5.5. In addition, Caelus has rightly asserted that in example 1, which as mentioned is directed to determination of which gut bacteria might influence insulin resistance in adult humans, *E. hallii* (as the species) is specifically mentioned as being advantageous: “In additional analyses, a significant association ( $r=0.8$ ,  $p<0.01$ ) was found between small intestinal *Eubacterium hallii* concentrations and the improvement in insulin sensitivity (Rd) in human subjects with metabolic syndrome 6

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<sup>5</sup> UPC CD Paris (20 April 2025), UPC CFI 230/2024

*weeks after lean donor fecal transplantation.*"([0052]). This other example clearly points to a broader scope therefore.

- 4.5.6. Caelus also made sufficiently clear that *E. hallii* should therefore be interpreted as *A. hallii* in modern terminology, while the claim further encompasses strain L2-7, at the priority date assumed to belong to *E. hallii* (but later reclassified as not a strain but a species called *A. soehngenii*<sup>5</sup>).

*hallii* on its own

- 4.5.7. Defendants further argue that the claims must be construed such that the patented *hallii* achieves the desired therapeutic effect "on its own". Defendants refer to an expert declaration by Caelus' expert Prof De Vos in the opposition proceedings at the EPO. In the report, Prof De Vos explains that example 3 provides the evidence that *hallii* is capable of achieving the beneficial therapeutic effects on its own, i.e. without any other bacteria that theoretically could have an effect according to example 1. In as far as this statement during the opposition proceedings would be binding on Caelus, the Court finds that the statement does not mean that the claims are realized if only *hallii* "on its own" causes the beneficial effect. It simply means that *hallii* is capable to do so but not that it is required for the claim. The claim contains no limiting feature to that effect.
- 4.5.8. This also follows from the description (paras. [0012], [0013], [0019] and [0029]). Paragraph [0019] is as follows, emphasis added:

The present disclosure also relates to a pharmaceutical, food, or feed composition comprising *Eubacterium hallii* et rel. and/or *Alcaligenes faecalis* et rel. for use in preventing and/or treating insulin resistance and/or related complications like dyslipidemia and type 2 diabetes mellitus. The pharmaceutical, food or feed composition preferably comprises an effective amount of trv. *Eubacterium hallii* et rel. and/or *Alcaligenes faecalis* et rel. Preferably, the pharmaceutical, food or feed composition comprises in total between about  $10^6$  and about  $10^{12}$ , preferably between about  $10^8$  and about  $10^{12}$ , bacteria of the taxon *Eubacterium hallii* et rel. and/or bacteria of the taxon *Alcaligenes faecalis* et rel. Preferably, said bacteria are contained in a daily dose.

It follows clearly that while the amount of *hallii* is preferably an effective amount, it does not necessarily prescribe this. This leaves open the possibility that *hallii* has a meaningful contribution to the effect but not that it is the only contributor. This is also apparent from the word "comprising" in this and other paragraphs. Paragraph [0029] furthermore describes the administration of *hallii* together with other lactic acid-producing bacteria and the resulting metabolic interaction. It does not imply that those other bacteria are or must be therapeutically irrelevant.

- 4.5.9. Thus, the patent and its description make clear that *hallii* may either be administered alone or in combination with other organisms which may contribute to the therapeutic effect. This contribution of *hallii* itself should be meaningful.

#### 4.6. Validity

- 4.6.1. The patent has undergone *inter partes* opposition and appeal proceedings at the EPO, after which the TBA upheld the patent in the form now subject of these proceedings (T 0250/23). This alone makes for a strong presumption of plausible validity of the patent. Defendants bear the burden of establishing that the Patent is more likely than not invalid.

#### Added matter

- 4.6.2. According to Defendants, claim 1 of the patent is invalid due to added matter. There is unallowable added matter if the claim as granted contains subject-matter that extends beyond the content of the application as filed. In order to ascertain whether there is added matter, the Court must thus first ascertain what the skilled person would derive directly and unambiguously using his common general knowledge and seen objectively and relative to the date of filing, from the whole of the application as filed, whereby implicitly disclosed subject-matter, i.e. matter that is a clear and unambiguous consequence of what is explicitly mentioned, shall also be considered as part of its content.<sup>6</sup> An intermediate generalization may add matter if the omitted features from an embodiment have a functional or structural relationship with the features left in the claim, giving rise to an inextricable link.<sup>7</sup>
- 4.6.3. Defendants' added matter objection is based on the proposition that "*E. hallii* et rel." constitutes a single and indivisible phylogenetic group, from which *hallii* cannot be isolated as an independent alternative. That objection is unfounded. The application as filed directly and unambiguously presents *hallii* and its specified relatives as alternatives and expressly discloses the therapeutic use of *hallii* as such. The application expressly identifies "*the butyrate-producing Eubacterium hallii*".<sup>8</sup> Example 3 further confirms that separate disclosure and does exactly what Defendants' interpretation supposedly excludes: administering *hallii* (without relatives), and reports "distinct effects" of administration of *hallii*. As mentioned above, the later qualification of L2-7 as a different species does not alter this teaching. The TBA did not decide on this argument as a ground of added matter but found the deletion of "et rel." did not extend the protection in a similar vein.

#### Insufficient disclosure

- 4.6.4. Defendants argue that the patent claims a species-wide therapeutic effect of the use of *hallii* based on experiments that are either too broad or only use one (later reclassified) strain, L2-7. According to Defendants, the skilled person would therefore need further research to identify which strains, doses and treatment conditions achieve the claimed effect across the full scope of the claim.

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<sup>6</sup> CoA 2 October 2025, expert klein v Seoul Viosys, UPC\_CoA\_764/2024 and UPC\_CoA\_774/2024

<sup>7</sup> CoA 14 February 2025, Abbott v Sibio, UPC\_CoA\_382/2024, paragraph 78, see also Case Law BoA EPO, II.E.1.9

<sup>8</sup> Patent Application, p. 5, r. 15-16.

- 4.6.5. In the preliminary opinion of the Court, examples 1 and 3 provide a coherent and credible experimental basis for the claimed therapeutic effect. Example 1 showed improved insulin sensitivity in human patients following allogenic faecal transplantation and identified an association between that improvement and increased intestinal levels of *hallii* and *A. faecalis*. Example 3 independently confirmed that oral administration of *hallii* could normalize insulin resistance in mice. These results support that the claimed invention could be carried out and achieve the therapeutic effect specified in claim 1. The TBA likewise concluded that Example 1 contains “a credible explanation, supported by extensive experimental evidence”<sup>9</sup>, while Example 3 “further supports the conclusions”<sup>10</sup> observed in Example 1. Again, the later qualification of L2-7 as a different species does not alter this teaching.
- 4.6.6. Defendants’ reliance on the absence of dosage and formulation parameters from claim 1, does not render the invention undisclosed. The patent (application) defines an “effective amount”, explains the patient- and disease-specific factors relevant to dosage and states that the skilled person can determine appropriate dosages.<sup>11</sup> It also discloses preferred daily quantities and detailed oral formulations.<sup>12</sup> These are routine implementation matters for the skilled person As confirmed by the UPC CoA: “A reasonable amount of trial and error does not prevent the invention from being enabled.”<sup>13</sup> Caelus rightly points out that Defendants have not identified a parameter that requires inventive effort or imposes an undue burden.
- 4.6.7. In conclusion and in view of the TBA’s findings, Defendants have not shown that the patent is more likely than not invalid for insufficiency.

#### Inventive step

- 4.6.8. The legal standard applied by both the UPC and the EPO when assessing inventive step, i.e. Art. 56 EPC, stipulates that an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. The principles to assess inventive step were set out by the Court of Appeal of the UPC on 25 November 2025 in the Amgen v Sanofi case and in the Edwards v Meril case. The Court of Appeal has confirmed that despite any differences between the approach of the UPC and the approaches of the EPO and/or national courts of the various EPC countries, all of these, when properly applied, should and generally do lead to the same conclusion.
- 4.6.9. The burden and presentation of proof with regard to the facts from which the lack of validity of the patent is derived and other circumstances favourable to the invalidity or revocation lies with the claimant in a revocation action (Art. 54 and 65(1) UPCA, R. 44(e)-(g), 25.1(b)-(d) RoP). Even though proof of certain facts, if contested, may be required, the assessment of whether the legal consequence for which the facts and

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<sup>9</sup> para. 5.5.

<sup>10</sup> para. 5.7.

<sup>11</sup> paras. [0012] and [0031].

<sup>12</sup> paras. [0019], [0022]-[0024].

<sup>13</sup> UPC\_CoA\_528/2024, UPC\_CoA\_529/2024 (*Amgen/Sanofi*), headnote 8.

circumstances have been submitted is justified, is a question of law. The approach taken by the Unified Patent Court when establishing inventive step, which can already be derived from the Order of the Court of Appeal in *Nanostring/10X Genomics* (supra), is as follows.

- 4.6.10. It first has to be established what the object of the invention is, i.e. the objective problem. This must be assessed from the perspective of the skilled person (m/f – hereinafter referred to as 'it'), with its common general knowledge, as at the application or priority date (also referred to as the relevant date) of the patent. This must be done by establishing what the invention adds to the state of the art, not by looking at the individual features of the claim, but by comparing the claim as a whole in context of the description and the drawings, thus also considering the inventive concept underlying the invention (the technical teaching), which must be based on the technical effect(s) that the skilled person on the basis of the application understands is (are) achieved with the claimed invention. In order to avoid hindsight, the objective problem should not contain pointers to the claimed solution.
- 4.6.11. The claimed solution is obvious when at the relevant date the skilled person, starting from a realistic starting point in the state of the art in the relevant field of technology, wishing to solve the objective problem, would (and not only: could) have arrived at the claimed solution. The relevant field of technology is the field relevant to the objective problem to be solved as well as any field in which the same or similar problem arises and of which the person skilled in the art of the specific field must be expected to be aware. A starting point is realistic if the teaching thereof would have been of interest to a skilled person who, at the relevant date, wishes to solve the objective problem. This may for instance be the case if the relevant piece of prior art already discloses several features similar to those relevant to the invention as claimed and/or addresses the same or a similar underlying problem as that of the claimed invention. There can be more than one realistic starting point and the claimed invention must be inventive starting from each of them.
- 4.6.12. The skilled person has no inventive skills and no imagination and requires a pointer or motivation that, starting from a realistic starting point, directs it to implement a next step in the direction of the claimed invention. As a general rule, a claimed solution must be considered not inventive / obvious when the skilled person would take the next step prompted by the pointer or as a matter of routine, and arrive at the claimed invention. A claimed solution is obvious if the skilled person would have taken the next step in expectation of finding an envisaged solution of this technical problem. This is generally the case when results of the next step were clearly predictable, or where there was a reasonable expectation of success.
- 4.6.13. The burden of proof that the results were clearly predictable or the skilled person would have reasonably expected success, i.e. that the solution he envisages by taking the next step would solve the objective problem, lies on the party asserting invalidity of the patent. 135. A reasonable expectation of success implies the ability of the skilled person to predict rationally, on the basis of scientific appraisal of the known

facts before a research project was started, the successful conclusion of that project within acceptable time limits.

- 4.6.14. Whether there is a reasonable expectation of success depends on the circumstances of the case. The more unexplored a technical field of research, the more difficult it was to make predictions about its successful conclusion and the lower the expectation of success. Envisaged practical or technical difficulties as well as costs involved in testing whether the desired result will be obtained when taking a next step may also withhold the skilled person from taking that step. On the other hand, the stronger a pointer towards the claimed solution, the lower the threshold for a reasonable expectation of success.
- 4.6.15. When the patentee brings forward and sufficiently substantiates uncertainties and / or practical or technical difficulties, the burden of proof that these would not prevent a skilled person from having a reasonable expectation of success, falls on the party alleging obviousness.
- 4.6.16. The fact that other persons or teams were working contemporaneously on the same project does not necessarily imply that there was a reasonable expectation of success. It may also indicate that it was an interesting area to explore with a mere hope to succeed.
- 4.6.17. Defendants present three inventive step attacks: (i) Gao<sup>14</sup> in combination with Louis<sup>15</sup>, (ii) Guilloteau<sup>16</sup>, and (iii) Sanz<sup>17</sup>. The Court finds it more likely than not that the patent will be held inventive, as did the TBA. The reasons are as follows.
- 4.6.18. Defendants formulate the objective problem as “the selection of an alternative therapeutic to treat or prevent insulin resistance in humans which does not have the drawbacks of poor pharmacodynamics with butyrate itself”. But that formulation is tainted with hindsight, as Caelus rightly asserts, as it assumes that (i) butyrate is the relevant therapeutic route, (ii) its direct administration in humans should be avoided, and (iii) an alternative means of providing butyrate should therefore be sought. The TBA expressly rejected a similar formulation because it contains a pointer to the claimed solution. The objective technical problem is therefore, as the TBA also held, *“providing a prevention or treatment of insulin resistance and/or the claimed insulin-resistance complications”*.
- 4.6.19. The Court preliminarily finds that the skilled person had no incentive to take the missing steps from any of the documents cited by Defendants:

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<sup>14</sup> Gao et al. (2009) "Butyrate improves insulin sensitivity and increases energy expenditure in mice," *Diabetes*, Vol. 58(7), pp. 1509-1517

<sup>15</sup> Louis et al. (2010) "Diversity of human colonic butyrate-producing bacteria revealed by analysis of the butyryl-CoA:acetate CoA-transferase gene," *Environmental microbiology*, Vol. 12(2), pp. 304–314

<sup>16</sup> Guilloteau et al. (2010) "From the gut to the peripheral tissues: the multiple effects of butyrate", *Nutrition research reviews*, Vol. 23(2), pp. 366–384

<sup>17</sup> Sanz et al. (2008) "Insights into the Roles of Gut Microbes in Obesity", *Interdiscip Perspect Infect Dis*, Vol. 2008, pp. 1–9

- a) **Gao in combination with Louis.** Gao points towards further studying butyrate or its derivatives in humans. It does not suggest replacing butyrate with a living microorganism capable of producing it. Louis investigates the presence and abundance of bacteria having a gene involved in butyrate production in the human gut. It does not teach administration of *hallii*, nor that administering *hallii* would result in therapeutically relevant butyrate production *in vivo*, and does not link *hallii* to any therapeutic effect on insulin resistance;
- b) **Guilloteau** reviews the biological effects of butyrate and discusses bacterial butyrate production in the context of the existing microbial ecosystem. It points to direct butyrate supplementation or to stimulation of endogenous butyrate production. It does not teach therapeutic administration of a living butyrate-producing organism, nor does it identify *hallii* as a therapeutic candidate; and
- c) **Sanz** likewise does not teach the claimed route. The TBA already considered what Sanz actually discloses. It found that *hallii* is mentioned only as one of several butyrate-producing bacteria in a section concerning energy metabolism and that Sanz does not contain a(n implicit) disclosure of using *hallii* for insulin resistance. In addition, Sanz explicitly discloses that there is an inverse relationship between Firmicutes, such as *hallii*, and body weight reductions. That hardly provides a reason to administer *hallii* for the claimed use.

4.6.20. The TBA rejected the same underlying reasoning and necessary sequence of choices. It found that those steps involved more than routine measures.

#### 4.7. *Infringement*

- 4.7.1. According to Defendants, they do not infringe because Caelus did not produce evidence that (i) the products contain the L2-7 strain, (ii) *hallii* is present in a therapeutically effective amount so that *hallii*, on its own, produces the claimed therapeutic effect, i.e. preventing or treating insulin resistance or insulin resistance-related complications and (iii) that the products produce the claimed therapeutic effect. The Court finds it more likely than not that both Metabolic Daily and Glucose Control fall within the scope of protection afforded by the patent for the following reasons.
- 4.7.2. As regards arguments (i) and (ii) the Court refers to its above claim construction. The claim is not limited to L2-7 and *E. hallii* (or rather: *hallii*) need not have the alleged therapeutic effect on its own, other bacteria may contribute. It is undisputed that *hallii* is present in both products. It is furthermore sufficiently plausible that *hallii* has a meaningful contribution to the effect. Defendants emphasize in their marketing materials that the products achieve the therapeutic effect and that *hallii* contributes to that effect. Pendulum describes *hallii* as a bacterium that boosts sugar metabolism, produces butyrate and supports GLP-1 production. It also explains that the bacterial strains in the Products convert fibre into butyrate, which stimulates GLP-1 production and affects glucose metabolism:

### *Anaerobutyricum hallii*

Another novel, next generation strain that's only available from Pendulum is *Anaerobutyricum hallii* (formerly called *Eubacterium hallii*). This unique strain is also not available in food, which is why it's important to take it as a daily probiotic. This strain boosts sugar metabolism, produces butyrate, and supports GLP-1 production.

- 4.7.3. Equally, Defendants launched the product Glucose Control as the first “*medical probiotic for people with type 2 diabetes*”:



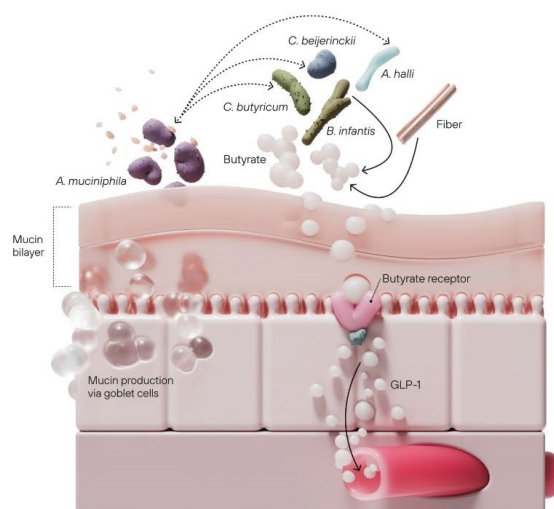
It describes medical probiotics as probiotics intended to deliver clinical efficacy in managing a particular disease or condition (emphasis added by Caelus):

### Pendulum Glucose Control is:

#### 1. Targeted

Pendulum Glucose Control is the only medical probiotic specifically designed for the dietary management of Type 2 diabetes.

- 4.7.4. Furthermore, the product webpage of Glucose Control includes a section ‘How it works’, which contains the following infographic:



### Controlling blood sugar naturally

#### 1- PRODUCES BUTYRATE

The probiotics in five-strain Glucose Control convert fiber in your gut into butyrate, a short-chain fatty acid.

#### 2 - INCREASES GLP-1\*

Butyrate stimulates your gut cells to produce GLP-1, a key hormone for controlling blood sugar.

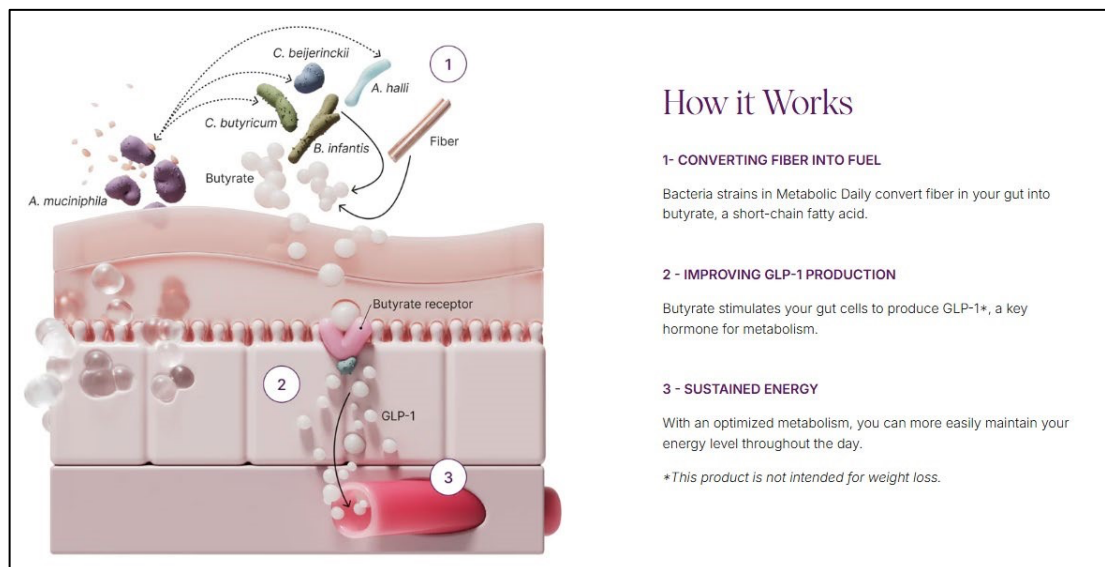
\*This product is not intended for weight loss.

#### 3 - IMPROVES GUT HEALTH

Glucose Control also helps maintain the integrity of your gut barrier, supporting overall gut health

The accompanying text explains that the probiotics in Glucose Control convert fiber into butyrate, which “stimulates your gut cells to produce GLP-1, a key hormone for controlling blood sugar”.

- 4.7.5. The same applies to Metabolic Daily. The product webpage of Metabolic Daily, like the page of Glucose Control, includes a section ‘How it works’, which contains the following infographic:



- 4.7.6. Like the Glucose Control infographic, the accompanying text explains that the bacteria strains in Metabolic Daily convert fiber into butyrate, which “stimulates your gut cells to produce GLP-1”.
- 4.7.7. Metabolic Daily is apparently the preventive version of Glucose Control. Pendulum’s CEO Dr. Cutcliffe describes it in Exhibit C47 as “the same formulation at a lower dose”. She adds that it is intended for people seeking to boost their sugar metabolism who are “not yet at the clinical stage of type 2 diabetes” (emphasis added by Caelus): We then launched Metabolic Daily, the same formulation at a lower dose, allowing us to reduce the price. It’s designed for anyone looking to boost their sugar metabolism but who is not yet at the clinical stage of type 2 diabetes.
- 4.7.8. This is consistent with what Dr. Cutcliffe says in an interview, where she says Metabolic Daily has “the efficacy of Glucose Control” (which is advertised as “a clinical-grade probiotic”), and explains that the hope is for people to use it “as a means of PREVENTING diabetes, so they never become Glucose Control customers in the first place” (emphasis added by Caelus):

Our flagship product, Glucose Control, was developed as a clinical-grade probiotic for people with type 2 diabetes to reduce A1C and lower blood sugar levels. However, there were also a lot of customers who didn't have type 2 diabetes who wanted to reap the metabolic benefits of the five powerful strains the product is formulated with.

We heard this feedback and created our newest probiotic, Metabolic Daily, which has the efficacy of Glucose Control but takes the form of a daily probiotic designed for everyone.

Our hope for this product is for people to take care of their metabolic health as an ongoing part of their wellness journey, as a means of PREVENTING diabetes, so they never become Glucose Control customers in the first place.

- 4.7.9. Without evidence to the contrary, Defendants may not now credibly claim that their products do not have this effect and/or that *hallii* does not contribute to this effect in a meaningful way. In fact, Defendants do not even claim this, they merely assert that Caelus did not produce the evidence, which is insufficient.

4.8. *Necessity, relief, balance of interests and costs*

- 4.8.1. In view of the likelihood of infringement and validity discussed above, the requested measures shall be granted in so far as necessary and proportionate.

- 4.8.2. The injunction will be granted for the UPC territory and for Switzerland, as requested. The Court fails to see that the above assessment would not equally apply in Switzerland, and no argument was forwarded by the Defendants to explain so. The provisionally established infringement warrants a general injunction. Caelus explained convincingly that an injunction is necessary at this moment. Caelus will suffer significant irreparable harm if Defendants' continuous and imminent infringement is not effectively addressed with the requested provisional measures. Defendants are establishing a first-mover position in the EU with its Products. If Caelus is forced to wait for a decision on the merits, the more its market exclusivity is irreversibly eroded. This results in irreparable and immediate harm and cannot be adequately compensated in damages after a decision on the merits. This is particularly pressing in view of the steps Caelus is currently taking in preparation for the launch of its own probiotic supplement in the EU. Under Regulation (EU) 2015/2283 (EU Novel food Regulation), the EFSA approval route is mandatory for food ingredients that were not consumed in the EU prior to 1997. A response from EFSA is expected by the end of July 2026. Defendants are commercialising the Products in Europe without having completed that regulatory route, creating an (unfair) advantage over Caelus. By the time Caelus has obtained regulatory approval and may enter the market, Pendulum will have set price points, locked in distribution channels and established brand recognition. All at the expense of Caelus' market exclusivity.

- 4.8.3. Defendants' interest to deny the preliminary relief sought appears minimal. In fact, by their own admission they claim there is no threat of infringement in the relevant territory. They assert that they have not sold or distributed any of the infringing

products in Europe and sales in Switzerland have stopped. While above it was concluded that this is incorrect (see chapter 4.2), it can be deduced that an injunction will have minimal impact on Defendant's business.

- 4.8.4. The alleged presence of another possibly infringing product on the market does not sufficiently alter that balance in this case, or at least it has not been sufficiently explained by Defendants, in view of Caelus' assertions.
- 4.8.5. The order for the provision of information, will be limited as set out in the order below. Information regarding distribution channels and the (further) origin of the products are deemed urgent and necessary for Caelus to prevent possible further infringement by third parties. Caelus has also explained why it has an urgent interest to know the quantities produced as claimed in (2): *"the quantities produced, manufactured, delivered, received or ordered are directly relevant to the scale of the infringement and to the appropriate scope of further relief. While the final quantification of damages can be addressed in proceedings on the merits, Caelus should not be required to await those proceedings before it can understand the scale and structure of the infringement and take effective steps to prevent its continuation."* In the light of this, Defendants' mere assertion that this is premature and for proceedings on the merits, is inadequate.
- 4.8.6. The requested order to deliver up any product in stock and / or otherwise held or owned by Defendants in the Contracting Member States where the patent is in force and Switzerland, is also considered proportionate to prevent further infringement. A term of two weeks is applied. Defendants did not sufficiently substantiate why this additional measure is not proportionate. The same applies to publication on the websites, however limited to the websites under control by Defendants 1 and 3. As noted above, it is assumed that iHerb ■■■ has enough control over the website to arrange this.
- 4.8.7. The requested recurring penalty payments are limited and maximised as set out in the order.
- 4.8.8. Caelus requests the Defendants to bear reasonable and proportionate legal costs and other expenses incurred by the Applicant in these proceedings as well as an interim payment of EUR 112,000. The Court applies the full ceiling as both sides have indicated they want reimbursement of the full ceiling. This shall be granted as requested. In this context, it is relevant that the value of this case is set at EUR 750,000, as requested by Caelus and not objected to.
- 4.8.9. Defendants requested to impose a security for enforcement of EUR 750,000. The Court rejects this. As the CoA held in *Abbott v Sibio*<sup>18</sup>, Defendants have not substantiated why serious difficulties would be expected in connection with the recovery of any possible damages from Caelus, a European based company. In addition, the request for security is irreconcilable with Defendants' claims that they are not on the market in the relevant countries.

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<sup>18</sup> CoA 14 February 2025, *Abbott v Sibio*, UPC\_CoA\_382/2024, paragraph 170.

## ORDER

### 5. The order is as follows

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

- 5.1. orders Defendants 1 and 3, within one week after service of this order, to refrain from infringing EP 2 753 187 B2 in any way, in particular by making, offering, placing on the market and/or using and/or importing or storing for those purposes products containing *Eubacterium hallii* (nowadays: *Anaerobutyricum hallii*) and/or *Alcaligenes faecalis* for use in the prevention or treatment of insulin resistance and/or related complications, including the products Glucose Control and Metabolic Daily, in Belgium, Denmark, Germany, France, Italy, the Netherlands, Sweden and Switzerland;
- 5.2. orders Defendants 1 and 3 to deliver up infringing products owned by, held by or for Defendants 1 and 3 in Belgium, Denmark, Germany, France, Italy, the Netherlands, Sweden and Switzerland within two weeks after service of this order, to prevent their entry into or movement within the channels of commerce in those countries;
- 5.3. orders Defendants 1 and 3, within four weeks after service of this order, to provide to Caelus (p/a of Brinkhof N.V.), a written account with information on:
  - (1) the origin and distribution channels of Glucose Control, Metabolic Daily, or any other product that falls within the scope of protection of EP 2 753 187 B2 within Belgium, Denmark, Germany, France, Italy, the Netherlands, Sweden and Switzerland;
  - (2) quantities produced, manufactured, delivered, received or ordered of Glucose Control, Metabolic Daily, or any other product that falls within the scope of protection of EP 2 753 187 B2 within Belgium, Denmark, Germany, France, Italy, the Netherlands, Sweden and Switzerland; and
  - (3) the identity, including full names and address details, of distributors, resellers, retailers and other legal entities involved in the sale, supply or distribution of Glucose Control, Metabolic Daily, or any other product that falls within the scope of protection of EP 2 753 187 B2 within Belgium, Denmark, Germany, France, Italy, the Netherlands, Sweden and Switzerland;
- 5.4. orders Defendants 1 and 3, at their own expense and within one week after service of the decision, to publish the following text  
*"We inform you that the Unified Patent Court on 8 October 2026 in a preliminary measure ordered us to refrain from infringing EP 2 753 187 B2 in any way, in particular by making, offering, placing on the market and/or using and/or importing or storing for those purposes products containing Eubacterium hallii (nowadays: Anaerobutyricum hallii) and/or Alcaligenes faecalis for use in the prevention or treatment of insulin resistance and/or related complications, including the products Glucose Control and Metabolic Daily, in Belgium, Denmark, Germany, France, Italy, the Netherlands, Sweden and Switzerland;"*

in English or respective local languages, without any additions or commentary, and to keep such publication available and clearly visible for a period of 4 weeks on the homepages of their respective websites (Art. 80 UPCA):

- (1) <https://pendulumlife.com/>
- (2) the country-specific domains of [iherb.com](https://iherb.com), of the UPC and EPC member states where the Patent is in force;

- 5.5. orders each Defendant to pay to the Court a penalty payment of EUR 50,000 for each day or part of a day that it does not comply with the injunction under 5.1, and EUR 50,000 for each day or part of a day that it does not comply in full with the orders under 5.3 and/or 5.4, such penalties to be determined by this Local Division upon request by Caelus, up to a maximum of EUR 10 million in total;
- 5.6. orders Defendants 1 and 3 to pay to Caelus an interim award of costs in the amount of EUR 112,000 within 14 days after service of this order;
- 5.7. orders the above immediately enforceable;
- 5.8. rejects the claims in all other respects;
- 5.9. determines that Defendants 1 and 3 shall bear the costs of the proceedings;
- 5.10. sets the date as referred to in R. 213.1 RoP at 30 calendar days after service of this order;
- 5.11. sets the value of the dispute at EUR 750,000.

|                                   |                                                                                                                                                                                                                                                 |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Brinkman                          | <b>Brinkman</b><br><b>Edger Frank</b><br>Digitally signed by<br>Brinkman Edger Frank<br>Date: 2026.10.08<br>11:56:24 +02'00'                                                                                                                    |
| On behalf of the Deputy Registrar | Digitally signed<br>Swinkels Nikki<br>2026-10-08 14:01:37 +0200<br> Unified Patent Court<br>Einheitsliches Patentgericht<br>Jurisdiction unifiée du brevet |

#### 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).