Intellectual Property Office

BL O/0550/23

13 June 2023

PATENTS ACT 1977

APPLICANT	SP NUTRACEUTICALS INC
ISSUE	Whether patent application GB2214988.4 meets the requirements for novelty and inventive step set out in the Patents Act 1977 (as amended)
HEARING OFFICER	Ben Buchanan

DECISION

Background

1 Application GB2214988.4 was filed in the name of SP NUTRACEUTICALS INC on the 11th December 2022 and is a divisional application of GB2001422.1 which was filed on the 10th July 2018 and claims priority from US application US62/532679 filed on the 14th July 2017. Application GB2214988.4 was published as GB2608759A on the 11th January 2023. The original agent for the application was Barker Brettell LLP, however a Form 51 was filed on the 14th February 2023 appointing Boxall IPM Ltd as the new representative. The original section 20 period for putting the application in order was the 11th January 2023 which has since been extended to the 11th May. This period has now passed, although it may yet be further extended at the discretion of the Comptroller under rule 108(3). Such a request would now, of course, be retrospective.

2 An initial Combined Search and Examination Report under sections 17 & 18 of the Patents Act 1977 (as amended), hereinafter referred to as the Act, was issued on the application on the 2nd November 2022. The request that the application be treated as having been filed on the 10th July 2018, the same date of filing as the earlier application GB2001422.1, was allowed. The report raised objections to the application on the grounds of novelty under sections 1 and 2 of the Act and inventive step under sections 1 and 3. Objections under clarity, section 14 of the Act, and presentation of information, section 1 of the Act, were also raised. In view of the nature of objections raised, and the timescale remaining to put the application in order, the Examiner invited the Applicant to request a hearing at this point.

3 The Applicant filed amended claims and arguments on the 6th January 2023, and requested a hearing if these were not accepted. The Examiner considered the amended claims and arguments but continued to regard the claims as not novel and inventive. A letter was issued on the 3rd February 2023 explaining their objections and the Examiner forwarded the application for consideration by a Hearing Officer.

4 The Applicant filed amended claims, arguments and supporting evidence on the 27th February 2023. On the 21st March the Applicant submitted skeleton arguments and requested a decision on the papers. The application has now come to me for a decision to be taken and this will be based on the claims filed on the 27th February. It is noted that the Examiner has not been able to formally consider these claims.

5 In coming to this decision I confirm I have taken account of all of the documentation on file.

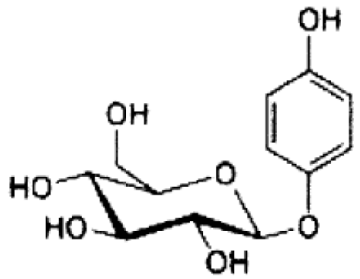
The invention and claims

6 The invention relates to methods and compositions for preventing or treating the formation or presence of nephroliths in mammals. More particularly the invention relates to methods and compositions comprising hydroquinone β-D-glucopyranoside of the structure of the formula given in claim 1 of the application for treating or preventing nephroliths in a subject.

7 The compound arbutin is metabolised in the body to form hydroquinone β-D-glucopyranoside, sometimes referred to as HQ (hydroquinone) in the prior art.

8 The amended main claim 1 of the application is as follows:

An anti-lithogenic pharmaceutical composition consisting of a compound having the structure of formula:



or a pharmaceutically acceptable salt or solvate thereof; and one or more pharmaceutically acceptable excipients, diluents, buffers, carriers or vehicles, for binding free and/or bound calcium oxalate for use in the treatment or prevention of calcium oxalate-based nephrolithiasis to reduce the size and/or number of nephroliths in a subject.

9 The compound shown in the claims is arbutin. It is worth noting that this claim requires that the composition *consists* of arbutin or a pharmaceutically acceptable salt or solvate thereof and one or more pharmaceutically acceptable excipients, diluents, buffers, carriers or vehicles. In the UK, “consisting of” is generally interpreted to mean “consisting exclusively of” whilst “comprising” is generally interpreted to mean “including” (i.e. other integers or features may be present)[1]. I will follow this convention in construing the claim. The composition defined in claim 1 therefore does not contain any other compounds beyond those noted in the claim. I

[1] Manual of Patent Practice section 14.123.1

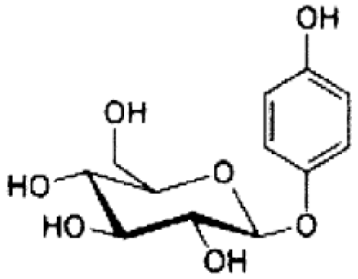
note that this phraseology reverses that used in the amended claims filed on the 6th January 2023, which itself replaced “consists of” (in the original claims) with “comprises”.

10 The claim requires that the composition is anti-lithogenic, that is it prevents the formation of calculi, calculi being stones, usually mineral salts that form in an organ or duct in the body. I note that the requirement that the compound *binds free and/or bound calcium oxalate* as required in the claim simply specifies the reaction that gives rise to the anti-lithogenic properties of the composition, whilst *calcium oxalate-based nephrolithiasis* simply refers to formations, more commonly known by the generic term of kidney stones. I note that “kidney stones” is a general term and includes other types of kidney stones as well as calcium oxalate-based nephrolithiasis.

11 In simple terms, claim 1 of the application therefore approximates to:

An anti-lithogenic pharmaceutical composition consisting of arbutin (or a pharmaceutically acceptable salt or solvate thereof) and one or more pharmaceutically acceptable excipients, diluents, buffers, carriers or vehicles for treating calcium oxalate-based nephrolithiasis.

12 There is a second independent claim in the application, main claim 4, which relates to the following:

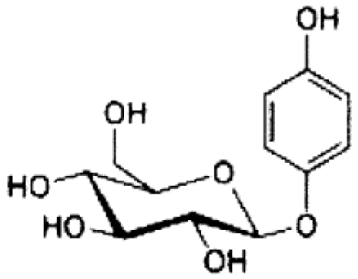


or a pharmaceutically acceptable salt or solvate thereof.

13 Once again the compound shown is arbutin. The claims are clear and there are no issues in construing their scope.

14 An auxiliary claim set was also filed for consideration. The auxiliary claim 1 is as follows:

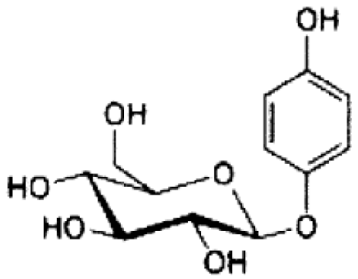
An anti-lithogenic pharmaceutical composition consisting of a compound having the structure of formula:



or a pharmaceutically acceptable salt or solvate thereof; and one or more pharmaceutically acceptable excipients, diluents, buffers, carriers or vehicles, for binding free and/or bound calcium oxalate for use in the treatment or prevention of calcium oxalate-based nephrolithiasis to reduce the size and/or number of nephroliths in a subject, wherein the amount of compound in the composition has an effective dose of from 50mg to 850mg/day.

15 There is also a second independent auxiliary claim, claim 3, which relates to the following:

A food composition for preventing or avoiding calcium oxalate nephrolithiasis in a subject, wherein the food composition comprises a compound having the structure of formula:



or a pharmaceutically acceptable salt or solvate thereof, wherein the amount of compound in the composition has an effective dose of from 50mg to 850mg/day.

I note that these claims differ from the main claim 1 and 4 only in that they specify an effective dose amount of compound in the composition.

The Law

16 Section 1(1) of the Act requires that:

A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say -

(a) the invention is new;

(b) it involves an inventive step;

(c) it is capable of industrial application;

(d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A below;

17 Parts (c) and (d) are not at issue and so I need to consider whether the application meets the requirements of S1(1)(a) and 1(1)(b).

18 Section 2(1) of the Act states that:

An invention shall be taken to be new if it does not form part of the state of the art.

19 Sections 2(2) and 2(3) of the Act relates to prior art and read as follows:

2(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

2(3) The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say -

(a) that matter was contained in the application for that other patent both as filed and as published; and

(b) the priority date of that matter is earlier than that of the invention.

20 Prior disclosure is therefore the first requirement to be satisfied for matter to anticipate an invention. To constitute a prior disclosure of an invention, the matter relied upon as prior art must disclose subject matter which, if performed, would necessarily result in infringement of the patent. This infringement test is detailed by the Court of Appeal in *General Tire & Rubber Company v Firestone*[2], at pages 485-6:

"If the prior inventor's publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty, that is to say, it will have been anticipated."

And then later

"…if carrying out the directions contained in the prior inventor's publication will inevitably result in something being made or done which, if the patentee's patent were valid, would constitute an infringement of the patentee's claim, this circumstance demonstrates that the patentee's claim has in fact been anticipated".

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[2] *General Tire & Rubber Company v Firestone Tyre & Rubber Company Limited, [1972] RPC 457*

21 Enablement is the second requirement for anticipation as held in *SmithKline Beecham*[3], in which it was stated that *"enablement means that the ordinary skilled person would have been able to perform the invention which satisfies the requirement of disclosure'* and that the skilled reader *'is assumed to be willing to make trial and error experiments to get it [the disclosed invention] to work"*.

22 With specific regard to medical use claims, Birss J in *Merck Sharp & Dohme*[4]*,* has noted that plausibility is an aspect of enablement, stating that *"In order to amount to an enabling disclosure of a medical use claim and thereby deprive the claim of novelty, the prior art has to make the therapeutic effect plausible.".*

23 Carr J established in *Actavis v Eli Lilly*[5] that the standard for plausibility does not require a reasonable expectation of success that the invention will work, as is required for inventive step. Something less is acceptable.

24 In *Merrell Dow*[6] Lord Hoffmann held that section 2(2) of the Act does not confine the state of the art about products to knowledge of their chemical composition. It is the invention which must be new and which must therefore not be part of the state of the art. It is therefore part of the state of the art if the information which has been disclosed in the prior art enables the public to know the product under a description sufficient to work the invention. Thus, in *Merrell Dow*, which centred on a claim to an acid metabolite formed in the liver after administration of terfenadine (itself the subject of an earlier patent), the acid metabolite was held to be anticipated not by prior use but because it was the inevitable result of carrying out the directions in the earlier terfenadine patent.

25 Lord Hoffman went on to hold that the use of a product makes an invention part of the state of the art only so far as that use makes available the necessary information. Thus acts, which are done without knowledge of the relevant facts but nevertheless would amount to infringement after the grant of the patent, will not count as anticipations before. In *Merrell Dow* the fact that volunteers in clinical trials had taken terfenadine and therefore had made the acid metabolite in their livers, was held not to constitute anticipation by use. The volunteers had been given terfenadine capsules for the sole purpose of swallowing them; they took them without knowing their composition and produced within themselves a substance, which was not then readily capable of being identified and was only later known to be the acid metabolite.

26 *Merrell Dow* was distinguished in *Evans Medical*[7] where a prior art vaccine had been made available to the public such that it would have been possible to analyse it to determine its contents. Actual prior identification of the process or product claimed was not in itself necessary to find a lack of novelty - merely instructions which, if followed, would inevitably result in the use of the claimed process or product. This was confirmed in *Halliburton*[8] where the Patents Court held that a dumb anticipation

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[3] *SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent [2006] RPC 10*
[4] *Merck Sharp & Dohme v Ono [2015] EWHC 2973; [2016] RPC 10*
[5] *Actavis v Eli Lilly [2015] EWHC 3294; [2016] RPC 12*
[6] *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd [1996] RPC 76*
[7] *Evans Medical Ltd's Patent [1998] RPC 517*
[8] *Halliburton Energy Services Inc v Smith International (North Sea) Ltd [2006] RPC 2*

(i.e. one not explicitly stating the invention) would be effective if it conveyed sufficient information to enable it to be dumbly reproduced.

27 Section 3 of the Act states that

An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above).

28 The test for inventive step is the well established test set out in *Pozzoli*[9], where Jacob LJ restated and elaborated upon the approach established in *Windsurfing*[10]. At paragraph 23 of *Pozzoli*, Jacob LJ reformulated the *Windsurfing* approach as follows:

> (1)(a) Identify the notional "person skilled in the art"
>
> (1)(b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

I will follow these steps where it is necessary to assess the obviousness of the invention defined in the claims.

Argument and analysis

29 When considering the claims for inventive step, and for novelty as will become clear, I first need to identify the person skilled in the art and their relevant background knowledge. In the Examiner's letter of 20th January 2023, the person skilled in the art and their relevant general knowledge is stated as:

a medicinal chemist working within the pharmaceutical sector. The common general knowledge of such a person includes an awareness of standard methodology for obtaining active pharmaceutical ingredients (APIs), including common means for obtaining plant extracts, and know of common pharmacores that are present in widely used drug molecules. A medicinal chemist would also have basic chemistry skills including the separation of mixtures by various chromatographic techniques, including chiral HPLC. Such a skilled person would also know how to incorporate APIs, and plant extracts, into a dosage form suitable for administration.

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[9] *Pozzoli SPA v BDMO SA [2007] EWCA Civ 588*
[10] *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd, [1985] RPC 59*

30 The Applicant indicated agreement in their letter of the 27th February 2023[11] and I will adopt the definition here.

Prior art

31 The Combined Search and Examination Report issued by the Examiner on the 2nd November 2022 noted three documents that were thought to be relevant at that time. These documents were:

D1: Integrated Laboratory Systems, Inc., January 2006, Chemical Information Review Document for Arbutin [CAS No. 497-76-7] and Extracts from Arctostaphylos uva-ursi, nih.gov, Available from https://ntp.niehs.nih.gov/ntp/htdocs/chem_background/exsumpdf/arbutin_508.pdf

D2: CN 102743586 A (WANG)

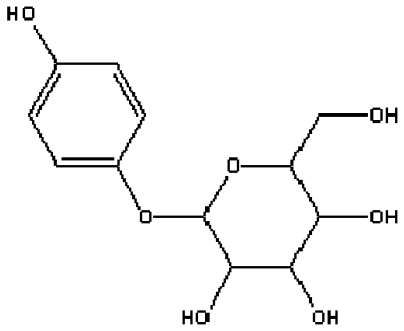
D3: US 2013/0064912 A1 (BARRON)

32 The documents have been referred to as simply D1, D2 and D3 respectively throughout the application process and I will adopt similar nomenclature here.

33 The abstract of D1 states that:

Arbutin is found in the dried leaves of a number of different plant species including bearberry (Arctostaphylos uva-ursi). The leaves and leaf extracts from uva ursi are used in non-prescription medicinal products mainly to treat urinary tract infection, cystitis, kidney stones, and as a diuretic. The active component, arbutin, is converted to hydroquinone (HQ) which has antimicrobial, astringent, and disinfectant properties.

Arbutin
[497-76-7]



[11] At page 8, line 1

35 It is therefore clear that the disclosure in D1 relates to the same compound as that defined in claim 1 of the application. The compound is arbutin. The introduction of D1 states that:

Uva ursi contains HQ derivatives (mostly arbutin), polyphenolic tannins, free-form phenolic acids, flavonoids, triterpenes, monotropein, resin, volatile oil, and wax.

36 And goes on to note:

The leaves are used in medicinal products, mainly to treat urinary tract infection, cystitis, and kidney stones. The active compound in uva ursi, arbutin, is converted to HQ, which has antimicrobial, astringent, and disinfectant properties.

37 It is clear from D1 that arbutin was thought to be the compound that gives rise to the medicinal properties of the plant leaf. The medicinal uses of the plant leaf known at the time of D1 include treatment of, amongst other things, kidney stones.

38 The abstract of D2 states that:

The invention discloses a medicine for treating kidney stone and gall-stone, according to a calculus formation pathology and a pharmacological experiment formula, the medicine of the invention is prepared by arbutin, desmodium, lichee nucleus, longan nucleus, common fenugreek seed, gecko, pig iron cinder, gynostemma pentaphylla, plantago, Orthosiphon Stamineus, Caulis aristolochiae manshuriensis, bletilla rhizome, magnolia cortex and sweetleaf tea.

39 It is therefore clear from D2 that a compound that includes arbutin may be used to treat, amongst other things, kidney stones.

40 D3 sets out a way of treating various ailments by *"…utilizing a nutritional composition comprising a complementary combination of homeopathic and traditional medicine components or ingredients. Use of the components singularly generally does not produce the desired effect of relief from the symptoms of kidney stones and/or gallstones. However, it has been discovered that the advantageous effects of reducing and/or alleviating the symptoms associated with kidney stones and/or gallstones can be achieved by combining the ingredients in a multi-component formula.".*

41 The most relevant parts of D3 are found in paragraphs [0053]-[0055]

[0053] One bioactive constituent of Uva Ursi (Arctosyaphylos uva ursi) is a glycoside called arbutin… In addition it has anti-lithic properties that help in dissolving crystals not just in the kidneys, but throughout the body as well…

[0054] In one embodiment, Uva Ursi (Arctosyaphylos uva ursi) tincture may be prepared from the leaves of the plant.

[0055] In addition to the homeopathic and traditional and/or nutraceutical ingredients described above, a nutritional or medicinal composition for the alleviation and/or prevention of the symptoms associated with kidney stones and gallstones can include one or more adjunct ingredients…

D3 therefore teaches that arbutin, in combination with other compounds, should be used to treat kidney stones. It teaches away from using arbutin alone.

Novelty

42 In the skeleton arguments of 21st March 2023, which addresses the objections made in the Examiner's letter issued on the 20th January 2023, it is argued that the claimed invention is distinguished by:

"In particular, the present invention resides in the selection of arbutin per se as an anti-lithogenic compound to bind free and or bound oxalate for treatment or prevention of calcium oxalate-based nephrolithiasis to reduce the size and/or number of nephroliths in a subject."

43 There are five separate parts to this distinction:

i) The composition relates to arbutin *per se*

ii) arbutin has anti-lithogenic properties

iii) arbutin binds free and or bound oxalate

iv) The composition is for treatment or prevention of calcium oxalate-based nephrolithiasis

v) The composition is used to reduce the size and/or number of nephroliths in a subject

44 In the Applicant's arguments of the 6th January 2023, 27th February 2023 and the skeleton arguments filed on the 21st March 2023, much is made of the different (allegedly contradictory, or at least non-complimentary) disclosures of the cited prior art, and the impermissibility of hindsight. The evidence filed on the 27th February is relied upon in the accompanying letter to support the arguments made in favour of the properties of arbutin and the appropriate dosage range for treatment. The argument acknowledges that D1 discloses arbutin as the active ingredient, but disputes that the property in question is taught as relevant to parts ii) – v) of the distinction above.

45 The Examiner asserts that D1 discloses arbutin is the active ingredient and that – notwithstanding its properties relevant for the treatment of other complaints – it is effective in the treatment of kidney stones. In a nutshell, this is because of the inevitable processing and action of the compound in the body, therefore parts ii) – v) of the argued distinction are inherent. Hindsight is not necessary because the action is disclosed, albeit not described in similar terms in D1. When considering novelty, this is paramount. That D3 (perhaps in error) appears to teach away from treating kidney stones with arbutin alone is immaterial for novelty. What is key is that the act of using arbutin to treat kidney stones, as disclosed in D1, would infringe the claimed patent.

46 I will not dissect every aspect of each argument and all the evidence. They are on file for all to see. What I will do is consider the prior art in light of each argument and the prevailing law, and come to a conclusion of my own.

47 It is clear from the prior art that only D1 gives clear directions to use a compound consisting of arbutin and a suitable carrier or vehicle. D2 and D3 both require the addition of other compounds. As such, since the main claim is now once again limited to a composition *consisting* of arbutin, only D1 meets this requirement and discloses part i) of the Applicant's five part distinction above.

48 D1 discloses that the leaves of *uva ursi* are *"used in medicinal products, mainly to treat urinary tract infection, cystitis, and kidney stones."* It goes on to note *"[t]he active compound in uva ursi, arbutin, is converted to HQ, which has antimicrobial, astringent, and disinfectant properties.".* Whilst D1 lists other compounds in the *uva ursi* leaf, there is no suggestion in D1 that any other compound in the leaf is responsible for the therapeutic effect of the leaf. Indeed D1 states that the active ingredient is arbutin and is silent on any other active ingredients in the leaf. D1 therefore discloses that the active ingredient in the leaves of *uva ursi* is arbutin and that the leaves of *uva ursi* can be used to treat kidney stones. Based on this, the skilled person reading D1 would recognise that it is plausible, and indeed would be expected that arbutin, the active ingredient in *uva ursi* leaves, can be used to treat kidney stones because it is anti-lithogenic, according to distinction ii) of the Applicant's argument.

49 Such a conclusion is consistent with *Merrell Dow* and follows the reasoning used therein. In particular in *Merrell Dow*, the following analogous example was given:

"Imagine a scientist telling an Amazonian Indian about the discoveries of 1820 and 1944. He says: "We have found that the reason why the bark is good for fevers is that it contains an alkaloid with a rather complicated chemical structure which reacts with the red corpuscles in the bloodstream. It is called quinine." The Indian replies: "That is very interesting. In my tribe, we call it the magic spirit of the bark." Does the Indian know about quinine? My Lords, under the description of a quality of the bark which makes it useful for treating fevers, he obviously does. I do not think it matters that he chooses to label it in animistic rather than chemical terms. He knows that the bark has a quality which makes it good for fever and that is one description of quinine."

The analogy holds for the realisation of the anti-lithogenic property of arbutin because D1 conveys sufficient information.

50 Moving on to the requirement that the compound be used to treat calcium oxalate-based nephrolithiasis, it was noted by the Examiner in their letter of 20th January 2023:

"Calcium oxalate stones are the most common type of kidney stone and this appears to be exceedingly widely known in the medical field. Up to 90 % of kidney stones comprise calcium (see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4708574/#r1) and calcium oxalate is present in 74 % of calcium stones acquired from the kidney and ureter (see https://pubmed.ncbi.nlm.nih.gov/10893570/). The prevalence of calcium oxalate stones means that they are always present in the mind of the skilled person when considering kidney stones and it is inherent that any compound active against a significant portion of kidney stones, such as arbutin is disclosed as being, must have an effect against calcium oxalate stones."

51 I agree with this reasoning and the skilled person reading D1 would recognise that calcium oxalate-based nephrolithiasis was being treated by the composition; this means that arbutin can be used to reduce the size and/or number of stones (nephroliths) in a subject and the skilled person would understand this from reading the information in D1. This meets parts iv) and v) of the argument above.

52 There is no clear statement in D1 that the arbutin is for "*binding free and/or bound calcium oxalate"* as required in claim 1 and noted in the third part of the distinction advanced by the Applicant's arguments. However, this reaction is inevitable when arbutin is used to treat kidney stones and will occur whether or not the person taking or administering the composition is aware that it is happening. Following similar reasoning to *Evans Medical* and *Merrell Dow* the disclosure of D1 therefore meets part iii) of the distinction argument above.

53 In short, D1 discloses that arbutin *per se*, with a suitable carrier or vehicle, may be used to treat kidney stones. When it is used to do so, the process is such that arbutin inevitably acts as an anti-lithogenic composition to bind free and or bound oxalate for treatment or prevention of calcium oxalate-based nephrolithiasis to reduce the size and/or number of nephroliths in a subject. The fact that there is no explicit recognition in D1 that arbutin "has anti-lithogenic properties, or that an active compound with anti-lithogenic properties is required for the prevention or treatment of calcium oxalate-based nephrolithiasis", as argued by the Applicant, is not relevant. It is sufficient that the cause and effect are known, and the mechanism is inevitable. Following similar reasoning to *Evans Medical* and *Merrell Dow*, D1 discloses subject matter which, if performed, would necessarily result in infringement of the patent as per *General Tire & Rubber Company v Firestone Tyre & Rubber Company Limited*. D1 therefore provides enabling disclosure and anticipates main claim 1 of the application. The same reasoning can be followed to show that the matter defined in main claim 4 of the application is also not novel, as incorporation of therapeutic compounds into foodstuffs such as tea and supplements is known.

54 I should acknowledge here the Applicant's argument on page 7 of their letter of the 27th February 2023 that the standard for plausibility does not require a reasonable expectation of success, and that if this applies to prior art as well as a patent, the question is one of inventive step. The question here is whether the prior art is enabling, not whether it is speculative. I consider the former to be satisfied and make no finding on the latter.

Inventive step

55 The independent main claims lack novelty and so I need not consider them for inventive step. Having said that, I think that the explicit and inherent disclosure of D1, disclosing the inevitable action of arbutin, would render the main independent claims obvious if I were wrong and they were deemed to be novel. Based on at least D1, the skilled person would be motivated to establish whether the action of arbutin alone can be exploited to treat kidney stones by virtue of anti-lithogenic properties. To do so would be within their skilled remit. They would be successful in treating calcium oxalate-based nephrolithiasis.

56 The inventiveness of the dependent claims need not be considered in detail here because I agree with the Examiner's reasoning in their letter of the 20th January

2023. Nonetheless, I will say that having considered them, with the exception of claims 3 and 6, they would appear to me to fall readily within the knowledge of the skilled person and so to be obvious in light of D1.

57 I note that the features defined in dependent claims 3 and 6 of the main claims are identical to those incorporated in the independent claims of the auxiliary request and these are the only differences. In considering the inventiveness of main claims 3 and 6 then, I will, by extension, be considering the auxiliary claims.

58 Main claims 3 and 6 (and the addition to the auxiliary independent claims) specify that:

"the amount of compound in the composition has an effective dose of from 50mg to 850mg/day"

59 D1 is silent on the specific dose of the compound and so, as the Examiner has acknowledged, does not anticipate this feature. I will therefore move on to considering whether or not the claims in question define subject matter which provides the required inventive step, following the procedure originally set out in *Windsurfing* and as updated in *Pozzoli.*

60 I have already considered both parts of step (1) of the test, identifying the skilled person and their common general knowledge, above.

61 The inventive concept in this instance appears to be the selection of arbutin *per se* as an anti-lithogenic compound to bind free and or bound oxalate for treatment or prevention of calcium oxalate-based nephrolithiasis to reduce the size and/or number of nephroliths in a subject, with the further specification of a particular dosage.

62 Following the reasoning given above, the only difference between this and the disclosure of D1 is the particular dosage. Given their common general knowledge I am confident that the skilled person would be able to establish the required dosage based on purely routine experimentation and so the specific dosage cannot, in itself provide the required inventive step. The composition defined in main claims 3 and 6 and the independent auxiliary claims would therefore have been obvious at the priority date of the invention. Following similar reasoning to that above, the remaining auxiliary claims also lack an inventive step.

Clarity

63 Clarity is not the matter at issue, and I will not consider it. However, I note that the Examiner objected to the claims as originally filed, in their examination report of the 2nd November 2022 in paragraph 12, as being unclear because they cannot define a composition which *consists of* arbutin *and comprises* additional agents. The amended claims considered in this decision would seem to re-introduce this contradiction. I do not believe this materially affects my decision. Even if the features relating to the additional agents were included, they would seem to fall squarely within the common general knowledge of the skilled person.

Conclusion

64 The main claims of the application lack novelty as required under section 1(1)(a) of the Act. Claims 2, 5, 7 and 8 also lack novelty. Main claims 3, 6 and all of the auxiliary claims lack an inventive step as required by section 1(1)b of the Act. Consequently, the application is refused under section 18(3).

Appeal

65 Any appeal must be lodged within 28 days after the date of this decision.

Ben Buchanan

Deputy Director, acting for the Comptroller