Intellectual Property Office

BL O/435/14

08 October 2014

PATENTS ACT 1977

APPLICANT	Gene Onyx Limited
ISSUE	The Patents Act 1977: whether patent application GB1313219.6 complies with Sections 1(2) and 14(3) of the Act
HEARING OFFICER	Dr L Cullen

DECISION

Introduction

1 This decision concerns patent application GB1313219.6 entitled "*Product selection using genetic analysis*" in the name of Gene Onyx Limited. This application was filed under the provisions of the Patent Cooperation Treaty (PCT) on 24 July 2013, claiming an earliest priority date of 20 December 2012, and was initially published as WO 2013/093407 A1 on 27 June 2013. On entering the national phase in UK, it was subsequently re-published as GB 2501640 A on 30 October 2013.

The application

2 The application relates to a method of using genetic analysis to assess the suitability of active ingredients in skincare, cosmetic, cosmeceutical or nutricosmetic products for use by an individual. In the discussion below, I will refer to these types of products collectively as cosmetic products and their impact as cosmetic activity.

3 Genetic analysis is used to assess if the active ingredients in these cosmetic products will be effective in an individual in terms of achieving a particular outcome, for example, treatment of dry skin. The response to these active ingredients in the individual may be a so-called 'direct response' or an 'indirect response' depending on which biochemical pathway in that individual these active ingredients target to exert their cosmetic activity. The genetic analysis focuses on what are known as single-nucleotide polymorphisms (SNPs) which are "hot spots" of variation in an individual's genome[1]. These variations in the genome are responsible for an individual's susceptibility to, or lack of response to, biologically or, in this case,

[1] The *genome* is the genetic material of an organism, in this case a human. It is encoded either in DNA or, for many types of viruses, in RNA. The genome includes both the genes and the non-coding sequences of the DNA (or RNA).

cosmetically active compounds. The method of the invention sets out a strategy, based on the analysis of a sample of genetic material from the individual, for the identification of the presence or absence of SNPs in that individual's genome which indicate a direct-response or an indirect-response relationship to each specific compound with a cosmetic activity. These specific compounds may be used singly or, as is more common, in combination with other cosmetic compounds as ingredients of various commercially available cosmetic preparations. The method associates a 'weight' to each SNP that is identified with each individual specific compound. This weight is based on how the specific compound interacts with the SNP in question, for example, a first-type interaction – i.e., direct binding of the compound to the protein that the SNP codes for, such as a receptor, or a second-type or indeed third-type of interaction which may involve an indirect response, for example, the specific compound interacts with the proteins, enzymes or co-factors involved in a downstream signalling mechanism. The weights for an active compound can then be worked out and used to give an indication whether or not this active compound would be beneficial, non-beneficial or possibly harmful to the individual in question.

Background

4 A number of rounds of written and oral communication took place between the Examiner and the Applicant concerning this application. The first official examination report (dated 25 September 2013) stated that the invention lacked patentability under Section 1(2) of the Patents Act 1977 (hereafter "the Act") because invention as claimed relates to a method of performing a mental act and/or a computer program. The examiner also raised objections under novelty and inventive step as well as to support and clarity.

5 In light of the arguments and amendments received from the applicant in their letter dated 22 November 2013, a second Examination Report was issued, dated 4 December 2013, in which the Examiner, following further consideration, stated that he was of the opinion that the application also lacked sufficiency under Section 14(3) of the Act. He considered that the application as filed did not disclose matter in enough detail for a skilled person to be able to carry out the invention

6 Despite further arguments presented by the Applicant in writing and by telephone, the Examiner, in his third Examination Report dated 26 February 2014, maintained his view that the application was insufficient and lacked patentability. In light of this lack of progress, the examiner suggested that a hearing was the best course of action. In their letter dated 3 March 2014, the agent requested a hearing on the outstanding issues on the case.

7 On 23rd May 2014, the Examiner issued an official letter setting out the matters to be considered at the hearing, namely, the issue of sufficiency under Section 14(3) of the Act and that of excluded matter as a mental act and/or a computer programme under Section 1(2)(c) of the Act.

8 The applicant provided a skeleton argument, including a witness statement, and a set of amended claims which were received at the Office on 9 June 2014. This skeleton argument was very helpful in setting out the applicants views on the matters

at issue and I thank the applicant for providing this material in advance of the hearing.

9 The matter came before me for an oral hearing at the Office in Newport on 11 June 2014. The applicant was represented by Dr Robert Lind of Marks & Clerk LLP. Dr Belinda Nedjai-Hunault, head of Genetics Research for the applicant was also in attendance. The examiner, Dr Jeremy Kaye, also attended. I was assisted at the hearing by Dr Bill Thomson, a senior patent examiner at the IPO.

Other matters arising at the hearing

10 Dr Lind enquired whether the outstanding objections relating to novelty and inventive step could be dealt with at the hearing. The Hearing Officer stated that the only matters before him for decision related to patentability and sufficiency as set out in the letter from the applicant dated 3 March 2014 requesting a hearing and the official report dated 23 May 2014 issued by the examiner concerning the issues to be dealt with at the hearing.

11 Dr Lind also provided an amended claim set filed as an "auxiliary request" with the skeleton argument on 4 June 2014. Dr Lind stated that these amended claims make more explicit the aspect of the invention dealing with the association of the cosmetically active compound(s) with the identified SNPs. He proposed that if I was minded to refuse this application as currently on file, that I would consider these amended claims before doing so. I indicated that it was necessary for me to consider the current set of claims on file and determine the issue of patentability and sufficiency in relation to these claims. The amended claims had not been filed formally at the IPO as a replacement for the current claims on file nor had they been considered by the examiner under Section 18 of the Act.

The claims

12 The claims at issue were those filed on 22 November 2013 and include only one independent claim which reads as follows:-

> "*A method of assessing the suitability of a set of available cosmetic and/or nutricosmetic and/or skin care products for an individual, each of said products containing a different set of active ingredients, the method comprising:*
>
> *testing a sample of genetic material from an individual to identify the presence or absence of single-nucleotide polymorphisms at a predefined set of single-nucleotide locations;*
>
> *identifying one or more weights for each location in dependence upon the presence or absence of a single-nucleotide polymorphism at the location; and*
>
> *associating each of a predefined set of active ingredients with one or more of said single-nucleotide locations, combining the location weights for the single-nucleotide locations associated with each active product ingredient to determine an ingredient score, and, for a given product, identifying the active ingredients in the product and determining a product score for each of said products using the*

associated ingredient scores, a score being indicative of the suitability of a product to the individual."

13 Dependent claims 2-11 further define aspects of the genetic testing process.

Issues to be decided

14 There are two issues to be decided in relation to this application. Firstly, does the application relate to subject matter that falls within the exclusions listed in Section 1(2) of the Act and is thus deemed not to be an invention for the purposes of the Act. In particular, does this application relate to a mental act and/or a computer program as such.

15 Secondly, does the application meet the requirement under Section 14(3) to disclose the invention in a manner that is clear and complete enough for it to be performed by a person skilled in the art.

16 I will deal with the issue of excluded matter under Section 1(2) first because, if I find that the invention does indeed fall within the provisions of this section of the Act, there will be no need to go on and consider if the invention is disclosed in sufficient detail.

Excluded Matter – Section 1(2)

The Relevant Law

17 Section 1(2) of the Act sets out certain categories of invention that are not patentable as follows:

> *"It is hereby declared that* ***the following*** *(among other things)* ***are not inventions for the purposes of this Act****, that is to say, anything which consists of –*
>
> *(a) …..;*
>
> *(b) …..;*
>
> *(c)* ***a*** *scheme, rule or* ***method for performing a mental act****, playing a game or doing business,* ***or a program for a computer****;*
>
> *(d) the presentation of information;*
>
> *but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such."*

18 Current IPO examination practice is to use the structured approach set out by the Court of Appeal in its judgment in *Aerotel/Macrossan* (hereafter *Aerotel*)[2] for deciding whether an invention is patentable. The test comprises four steps:

(1) Properly construe the claim;

[2] *Aerotel Ltd v Telco Ltd;, Macrossan's Patent Application* [2006] EWCA 1371, [2007] RPC 7

(2) Identify the actual contribution;
(3) Ask whether it falls solely within the excluded matter;
(4) Check whether the contribution is actually technical in nature.

Operation of this test is explained in paragraphs 40-48 of the *Aerotel* judgment. Paragraph 43 confirms that identification of the contribution is essentially a matter of determining what it is that the inventor has really added to human knowledge and involves looking at the substance of the invention claimed, rather than the form of the claim. As Jacob LJ states in this paragraph "*it is an exercise in judgment probably involving the problem said to be solved, how the invention works, what its advantages are. What has the inventor really added to human knowledge perhaps best sums up the exercise. The formulation involves looking at substance not form – which is surely what the legislator intended."* Paragraph 44 states that, at the application stage, the contribution may be taken to be that alleged by the inventor, although this cannot be conclusive; as Jacob LJ states, "[*i]n the end the test must be what contribution has actually been made, not what the inventor says he has made*". Paragraph 46 explains that the fourth step of checking whether the contribution is technical may not be necessary because the third step – asking whether the contribution is solely of excluded matter - should have covered that point already.

19 More recently, the Court of Appeal in the case of *Symbian [2009] RPC 1* (hereafter *Symbian*) confirmed that this structured approach is one means of answering the question whether or not the invention reveals a technical contribution to the state of the art. In other words, *Symbian* confirmed that the four-step test is equivalent to the prior case law test of '*technical contribution'*, as discussed in *Merrill Lynch*[3], *Gale*[4] and *Fujitsu*[5]*.*

Argument and Analysis

20 The analysis below is based on the four step approach described in *Aerotel*.

Step (1): Properly construe the claim;

21 Construing claim 1 is straightforward. It describes a method for assessing the suitability of a set of cosmetics, nutricosmetics or skin care products for use on an individual and it comprises a number of steps. The method comprises the following steps – which I have numbered for ease of reference:

(i) testing a sample of genetic material from an individual to identify the presence or absence of single nucleotide polymorphisms (SNPs) at pre-defined locations;

(ii) identifying one or more weights for each location dependent upon the SNPs present at the location and

(iii) associating each of a set of active ingredients with one or more of the said SNP locations;

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[3] *Merrill Lynch's application* [1989] RPC 561.
[4] *Gale's application* [1991] RPC 305.
[5] *Fujitsu Limited's application* [1997] RPC 608.

(iv) combining the location weights to provide an ingredient score; and

(v) for a given product, identifying the active ingredients and determining a product score using the associated ingredient scores, a score being indicative of the suitability of a product to an individual.

22 I do not consider that any of these steps have a meaning other than that implied by a plain construction of the words used based on their usual meaning in the English language.

23 I consider that this claim describes a method where the genetic make-up of an individual is tested to identify if any, some or all, of a series of SNPs are present that indicate that an ingredient found in a cosmetic product will be impacted by that SNP and hence a cosmetic product containing that ingredient will have an impact on the individual, the degree of this impact will depend on the exact SNP identified. When all the SNPs identified have been considered against the different active ingredients in the cosmetic product or products under consideration, a comparison of the impacts of the active ingredients will provide an assessment of whether or not a particular cosmetic product which contains one or more these active ingredients will have an overall suitable outcome for that individual if used.

24 In his skeleton and at the hearing, Dr Lind argued that it was necessary to consider the meaning of the term 'weight' as used in this claim. Based on the claim and the examples in the specification as filed, he stated that this term refers to a value for use in a numerical method to calculate scores for each active ingredient as well as for each product, which is made up of at least one, but usually more, active ingredients. I do not consider that this relates to anything other than a normal construction of this term based on its use in the claim and thus I do not consider that anything turns on this point.

Step 2 – identify the actual contribution

25 As stated in *Aerotel,* this step is concerned with the answer to the question "What has the inventor really added to the sum of human knowledge?"

26 The examiner considers that the contribution made by this application is the procedure for the calculation and application of weights. He indentified the contribution as the application of weights to SNPs based on the level of interaction of specific compounds – be it a direct association – a so called "level 1" interaction – or a less direct interaction – a so called "level 2" or "level 3" interactions, i.e., involvement in some kind of downstream molecular interaction. He expressed the view that the means by which these weights are arrived at in the worked examples, as well as the fact that there was no indication as to how a weighting might actually be calculated, meant that the weights used, for example, in Table 4, were nothing more than arbitrary figures ranging from 0-20, where any calculation of such weights is considered to be a step that is subjective and non-technical in nature and is thus a mental act. Further, the examiner considered that if the weighting is carried out within a "*...point of sale terminal that is used by a sales person or beautician ("consultant") that is assisting a customer to select a suitable product*", then the method would relate to a computer program as such.

27 When asked to address this point at the hearing, Dr Lind stated that in order to understand the contribution made by this application it was necessary to first consider what was the state of the art. He then went on to explain how the invention differed over the state of the art. He took as his starting point the prior art document cited by the examiner WO02/080755 and then went on to explain how the current invention makes a contribution that is over and above what is disclosed in this prior art document. In his skeleton argument, he summarised "*the contributions over the state of the art are as follows:*

> *a) A selection of SNPs (to be tested for) based upon the active ingredients rather than conditions.*
> *b) An identification of one or more weights for each SNP location, where that weight is suitable for use in a numerical method to calculate an ingredient and product score, in dependence upon the presence or absence of a single-nucleotide polymorphism at the location.*
> *c) The use of the identified weights to determine, numerically, ingredient and product scores."*

However, while a knowledge of the state of the art does play a role in assessing the contribution, as Lewison J (as he then was) noted in paragraph 8 of the *AT&T* judgement[6], this does not necessarily mean that the contribution is defined by what is new and inventive in the claim. A consideration of 'what has been added to human knowledge' is the summation of all of the factors that go in to making up the contribution. It is necessary to look beyond the literal wording of the claims to consider what is the central idea embodied in the claims. As Jacob LJ referred to in Aerotel, additional factors that are relevant to identifying the contribution are: (a) *What problem does the invention purport to solve* - this may be stated explicitly or it may be have to derived from the nature of the invention; (b) *How does the invention work* as a matter of practical reality; and (c) what are *the advantages offered by the invention*, the latter are normally closely linked to the problem being addressed, in the sense that the advantage is often that the problem is resolved. All of these factors may assist in identifying the contribution, rather than defining it themselves.

28 Thus, focussing solely on the difference between what is disclosed in the prior art document WO02/080755 and what is disclosed in the application in suit, is not sufficient in my view to determine the contribution in this case. In making this determination, I am bound to follow the approach laid out in Aerotel which requires me to look at all relevant factors.

29 At the hearing, Dr Nedjai-Hunault explained that this application relates to a new way of using genetic analysis based on analysing the active ingredients and not the condition being targeted. Unlike the current approach used for the development of cosmetic products, which is to develop products which contain a range of active ingredients that are known to have a cosmetic impact, e.g. on the skin such as moisturisers, antioxidants, sun screens, collagen stimulation etc, the application in suit assesses the active ingredients directly in terms of how they will interact with an individual. A cosmetic product developed in the traditional way to treat skin, for

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[6] *AT&T Knowledge Ventures/Cvon Innovations v Comptroller General of Patents* [2009] EWHC 343 (Pat)

example, will contain the best selection of active ingredients to achieve an improvement based on exhaustive testing on a wide range of people to bring about some improvement in all cases. Each company will develop its own cosmetic product and put a lot of effort into selling and marketing its brand as an effective treatment for dry or wrinkled skin. This might be regarded as the "blockbuster" approach, similar to the way in which products are developed to treat medical conditions – identify the condition, identify a range of active ingredients that can bring about an improvement in that condition and then formulate them into a suitable medical product to treat people with that condition. This traditional approach to developing cosmetics is condition driven

30 In the application in suit, the approach being taken to determine the best cosmetic product to use for an individual is different, it is one based on the individual being treated and not the condition. It involves finding out which active ingredients work best in the individual based on their genetic make-up and then selecting, or preparing, a cosmetic product which has the best combination of active ingredients for that individual, or equally rejecting those cosmetic products that contain active ingredients which will not work well for that individual. Dr Nedjai-Hunault referred to this as a 'disruptive technology' because it is a very new approach and one which is focused on the impact of the active cosmetic ingredient being tested on the individual rather than on the condition being treated.

31 In his skeleton argument and at the hearing, Dr Lind placed a lot of emphasis on the so-called 'identifying step' in claim 1 (see (ii) above). In his skeleton argument, he described the significance of this step as being "*the allocation of a weight to a particular SNP location in dependence upon the result produced for that location. The possible weights will have been previously determined, e.g. at the backend laboratory, such that the identification is likely to include a "selection" of a weight from two or more available weights. Thus for example three weights may be available depending upon whether the SNP location is mutated, wild-type or heterozygous. As a result of this* [identifying] *step, a weight will be selected for all SNP locations tested*". He also brought my attention to the fact that there must be an association between each active ingredient and the one or more SNP locations that are being tested. In doing so he referred to page 6, lines 26-35 and page 7, lines 2-7, of the application as filed. Dr Lind considered that, in the user being tested, the association required in this part of the claim is representative of the efficacy of the biological pathway for processing the active ingredient in question. This association provides a means to decide how effective the active ingredient will be for an individual. As the description refers (at page 7, lines 9-18, as filed) this method matches the active ingredient to an SNP that is 'strong' enough to affect the efficacy of the ingredient – this effect may be to reduce the efficacy of the active ingredient, to eliminate the efficacy of this active ingredient or to increase this efficacy. The advantage of this method is that it can be used to identity what active cosmetic ingredients out of the many that are available will be most effective for an individual.

32 Dr Lind went on to explain that the method also includes the work that has to be done in order to identify what are the SNPs that are linked to each active ingredient. This work is done by identifying what biological pathway in the body is responsible for the processing a particular active ingredient found in cosmetic products and, as a

consequence, understanding which genes are responsible for coding for the proteins, enzymes, co-factors etc involved in this biological pathway. One will then also know that if a SNP is located on that gene, it will have an impact on the ability of the individual to process that active ingredient. There may be a number of SNPs that can occur on this gene and, if present, these will have an impact on the ability of the individual to process the active ingredient in the cosmetic. Each of these SNP locations is weighted based on the significance of this impact. The predefined SNPs to be tested referred to in claim 1 (see step (i) above) will thus depend on, firstly, knowing what the active ingredient is and, secondly, what are the most relevant SNP locations for that active ingredient. Based on which of these SNPs are found to be present, then the weight for each location tested is applied, said weight being a value that reflects the efficacy of the ingredient.

33 I find that there is merit in this argument from Dr Lind – in order to determine which cosmetic products are best to be used with an individual one has to determine all SNPs that are relevant and will have an impact on the cosmetically active ingredients in these products. Where more than one cosmetically active ingredient is present in a cosmetic product, one will have to work out the overall impact of the cosmetic product by adding up the impacts from all the relevant SNPs.

34 I consider that the contribution of the application in suit is the identification of SNPs at certain locations in the human genome and the association of these SNPs with certain cosmetically active compounds and the assignment of a value or weight to each SNP based on how each cosmetically active compound is affected by the identified SNP. The effect of concern in all cases is the effect on the ability of the active cosmetic ingredient to carry out its normal activity, i.e. to exert its impact on its biological target. In addition the contribution includes using the values so assigned to work out if the cosmetically active ingredients in a cosmetic product will be suitable for a human individual based on an analysis of the individual's genetic make-up. The weights given to each SNP depend on the impact it has on the active ingredient being considered and the resultant impact that this has on the ability of the active ingredient to deliver a cosmetic effect to the individual being tested.

35 The process of associating weights to SNPs based on the level of interaction of specific compounds – be it a direct association – a so called "level 1" interaction – or a less direct interaction – a so called "level 2" or "level 3" interaction, i.e., a molecular interaction in a downstream biochemical pathway – is part of the contribution made by the application. The examiner identified this as the sole contribution made by the application but I do not consider that this is the case. As I have indicated above, the contribution also includes identifying the locations of the SNPs in the human genome that have an interaction with different cosmetically active compounds and matching each SNP to the active cosmetic ingredients that it affects and assigning a value or weight to this SNP that reflects how significant is the interaction with the ingredient in terms of it being able to exert its cosmetic effect. It also includes the step of testing a sample of genetic material from an individual and identifying the SNP locations in their genome that will interact with the active cosmetic ingredient under consideration, and so determine what active cosmetic ingredients will have the best impact.

Step 3 - ask whether it falls solely within the excluded matter;

Step 4 - check whether the actual or alleged contribution is actually technical in nature.

36 Having identified the contribution as above, the key question that arises is whether or not this falls solely within matters that are excluded under Section 1(2) of the Act.

37 The work necessary to identify the SNPs that relate to one or more cosmetic ingredients requires analysis of the biochemical pathways that are used by the active cosmetic ingredients and identification of the genes which code for the various enzymes, proteins, co-factors etc., involved in each biochemical pathway. An SNP located on any of these genes will have an impact on the enzymes, proteins, co-factors etc., that they code for and hence on the how these enzymes, proteins, co-factors etc., will interact with the cosmetic active ingredient. Identifying what part of a gene codes for a specific enzyme, protein, or co-factors etc.; identifying what are the SNPs associated with these genes and what is the resultant impact on the enzyme, protein, or co-factors is a part of the contribution. The techniques to carry out such analysis are well known in the art but what is different in the application in suit is that the SNPs being identified and compared are those that relate to specific cosmetic ingredients rather than, as is usually the case, SNPs that relate to a particular condition or disorder being targeted.

38 Thus it is necessary to carry out work in the laboratory to identify what SNPs relate to what active cosmetic ingredients and how significant is the impact of these SNPs on the ability of the active cosmetic ingredients to deliver its usual cosmetic effect. It is clear that this process of identification of SNPs that relate to active cosmetic ingredients and their associated impact on an individual can be carried out using automated and computerised laboratory equipment and the results stored in a database for comparison purposes. Indeed the applicant refers to this in the application as filed on pages 13, lines 4-22.

39 It appears to me that there are two parts to the association of a value or weight to the SNP interaction with an active cosmetic ingredient. The first part is the step of identifying what are the SNPs in the human genome that will result in an interaction of some kind with the active cosmetic ingredient. As mentioned above, this can be worked out by identifying what enzymes, proteins, co-factors etc., interact with the active cosmetic ingredient and then determining what are the SNPs that will have a significant effect or impact on this active cosmetic ingredient. As explained in the application as filed this is referred to as the SNP Impact Factor or SIF and only SNPs with a high impact factor will be used when looking at the impact of an active cosmetic ingredient on an individual – a high impact may be one that has a significant positive impact or one that has a significant negative impact. The SIF is used to decide which of SNPs to use when testing for a particular active cosmetic ingredient. The applicant refers to this as the ‘efficacy of the ingredient’.

40 The second part to the association of a value or weight to the SNP interaction with an active cosmetic ingredient is that which is carried out once the SNPs to be tested for have been identified and this in turn is based on the significance of the interaction of the SNP with the cosmetic active ingredient to be tested for. As Figure 4 shows a list of active cosmetic ingredients in the cosmetic product which is proposed for treatment of an individual is matched to the possible SNPs that show an impact on that active cosmetic ingredient. The SNPs that relate to each active ingredient are

then compared and those with the highest impact for each are selected. The genetic sample from the individual is then analysed to determine if these SNPs are present. If present, the impact of each SNP is assessed and, where more than one SNP is present for each active cosmetic ingredient, the overall impact is worked out. This is a comparative process so the impacts determined are relative ones based on the genotype – whether wild-type, mutated or heterozygous and the level of interaction, whether first, second or third level. This information can be prepared for all active ingredients in a product set of interest and stored in a database (i.e. a weighting table) and can be made available as a point-of-sale terminal for use by a person such as a beautician or sales adviser that is assisting the individual to select a suitable cosmetic product.

41 It is well known in the art how to identify the SNPs in a gene and it is also well known what parameters are important to take into account when deciding on relevance of an SNP – see application as filed page 9, line 20 to page 10, line 4. However, as I have already noted above, what is new in this case is that the SNPs being examined are related to the active cosmetic ingredient and not to the condition being treated. Although, this information can be stored in a database or in table form for future reference and comparison, it is first necessary to identify the SNPs that relate to each active cosmetic ingredient.

42 Thus I do not consider that the contribution I have identified falls solely within excluded matter. The contribution, in my view, comprises a technical process that is carried out in the laboratory to identify what SNPs relate to what active cosmetic ingredients and how significant is the impact of these SNPs on the ability of the active cosmetic ingredients to deliver its usual cosmetic effect.

43 The decision in *Halliburton*[7] confirmed (in paragraphs 57 and 63) that the mental act exclusion is to be interpreted narrowly – it only covers acts that are carried out by "purely mental means", and does not extend to those which are merely capable of being performed mentally. The aim of this exclusion was to prevent patents being granted which could be infringed "*by thought alone*". In the judgment (in paragraph 43), HHJ Birss (as he then was) specifically outlined that, with this interpretation, a claim carried out on a computer could not be excluded as a mental act. Thus, if a computer (or any other hardware) is involved in the invention, it will not be excluded as a mental act. However, in such an instance the claim could still fall within the computer program exclusion.

44 As noted above the examiner considered that application in suit failed the mental act exclusion and, when carried out on a point-of-sale terminal, also failed the computer programme as such exclusion. However, as I have noted above the contribution of the application in suit does not solely involve the calculation of weights for SNPs based on the level of interaction of specific compounds in the manner suggested by the examiner.

45 As regards whether the contribution of the invention relates to a computer programme, a consideration of the first of the "signposts" set out by Lewison J (as he then was) in paragraph 40 of the *AT&T* judgment[6], further modified by Lewison LJ in

[7] *Halliburton Energy Services Inc's Applications* [2012] RPC 129

the *HTC* judgement[8], and recently set out in detail in *Lantana*[9] i.e. "*the claimed technical effect has a technical effect on a process which is carried on outside the computer*"*,* is relevant to the present case.

46 In this case, the task of determining whether or not a cosmetic product comprising a number of active cosmetic ingredients will result in an individual experiencing cosmetic efficacy from a cosmetic product comprising all these active cosmetic ingredients is one that can be regarded as a technical process which is carried on outside the computer.

47 I am therefore satisfied that the current application does not fall within the excluded matter provisions of the Act.

Sufficiency of disclosure – Section 14(3)

48 Having found that the invention is not excluded under Section 1(2) of the Act, I must now go on to consider if it meets the requirement under Section 14 of the Act for disclosure in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art. This is usually referred to as "sufficiency of disclosure" or "sufficiency".

The Relevant Law

49 Section 14(3) of the Act reads as follows:

> *"The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art."*

50 The provision under Section 14(3), which concerns patent applications prior to grant accords directly with Section 72(1)(c) which sets out the same requirement for the validity of the granted patent. While the case law referred to below relates, for the most part, to proceedings under Section 72, the principles set out in these cases are pertinent to Section14(3) as well as to Section 72(1)(c).

51 In *Eli Lilly*[10]*,* at paragraph [239], Kitchin J gave the following summary of the relevant principles, to be applied when assessing whether an application satisfies this Section of the Act:

> *"The specification must disclose the invention clearly and completely enough for it to be performed by a person skilled in the art. The key elements of this requirement which bear on the present case are these:*
> *(i) the first step is to identify the invention and that is to be done by reading and construing the claims;*
> *(ii) in the case of a product claim that means making or otherwise obtaining the product;*
> *(iii) in the case of a process claim, it means working the process;*

[8] *HTC v Apple* [2013] EWCA Civ 451.
[9] *Lantana Ltd's Application* [2013] EWHC 2673 (Pat)
[10] *Eli Lilly & Co. v Human Genome Sciences, Inc. [2008] RPC 29*

(iv) sufficiency of the disclosure must be assessed on the basis of the specification as a whole including the description and the claims;
(v) the disclosure is aimed at the skilled person who may use his common general knowledge to supplement the information contained in the specification;
(vi) the specification must be sufficient to allow the invention to be performed over the whole scope of the claim;
(vii) the specification must be sufficient to allow the invention to be so performed without undue burden."

52 The purpose of the requirements imposed by Section 14(3) and Section 72(1)(c) is to prevent a patentee laying claim to products or processes which the teaching of the patent does not enable the skilled addressee to perform as set out in the *Zipher* judgment[11]. Thus, the consideration of sufficiency in essence deals with the extent to which the applicant has provided an enabling disclosure for their invention.

53 It is the responsibility of the applicant to ensure that, at the time of filing of the application, the disclosure is clear and complete in respect of the invention claimed in each of the claims. If it is not, then either the application must be refused or, if it is possible to do so, the claims must be restricted to that matter which has been adequately disclosed i.e. that for which there is an enabling disclosure.

54 The House of Lords in *Biogen*[12] held that sufficiency should be decided at the date of filing of the application

55 The concept of the "person skilled in the art" is that of the uninventive, but technically competent person (or team) who is considered for the purpose of assessing inventive step under Section 2 of the Act. As stated by Aldous J in *Mentor Corporation v Hollister Inc.* [1991] FSR 557 (at page 561):

> *"The Section requires that the skilled man be able to perform the invention. Such a man is the ordinary addressee of the patent. He must be assumed to be possessed of the common general knowledge in the art and the necessary skill and expertise to apply that knowledge. He is the man of average skill and intelligence, but is not expected to be able to exercise any invention. In some arts he may have a degree, in others he will be a man with practical experience only. Further, in circumstances where the art encompasses more than one technology, the notional skilled addressee will be possessed of those technologies which may mean that he will have the knowledge of more than one person."*

56 However, although the phrase "person skilled in the art" is construed in the same way when considering sufficiency and inventive step, for the purposes of Section 14(3), the skilled person is seeking to make the patent work and does so with the common general knowledge at the time the patent was filed. In contrast to the situation where inventive step is under consideration, the skilled worker in this situation has the patent in front of them, and is "*trying to carry out the invention and achieve success,...not searching for a solution in ignorance of it*." (see *Zipher*

[11] *Zipher Ltd v Markem Systems Ltd* [2009] FSR 1
[12] *Biogen Inc. v Medeva plc [1997] RPC 1*

judgement at page 50). Thus the nature and skills of the skilled person (or team), need not be the same for both inventive step and sufficiency purposes.

Argument and Analysis

View of the Examiner

57 The Examiner essentially argues that it is not possible to calculate weights for SNPs or calculate "scores" for compounds or products using the information provided in the application. There is no clear indication of how different SNPs may be given different weights depending on whether they are present in a homozygous or heterozygous mutated form or indicative of varying degrees of function defect or function gain. There is also no indication of how the compounds may be associated with a particular SNP. Thus the examiner considers that the skilled person would be required to undertake a massive amount of additional work to identify the associations between SNPs and compounds and then if feasible, determine a weighing system and ingredient/product score.

58 In the official Examination Report dated 4 December 2013, the examiner laid out in detail his concerns regarding the sufficiency of disclosure in this application. He considered in detail the two worked examples in the application as filed, the first dealing with SNPs in the HM74 receptor with regard to the compound niacin in the product Strivectin SD (Example 1) and the second dealing with SNP1 MMP1 (Example 2) in relation to the skin product Elemis, a pro-collagen marine cream that contains niacin as an active ingredient. In Example 1, only two SNPs in the HM74 receptor are looked at – His253Arg and Phe198Leu - with no other SNPs being discussed. The Examiner argued it was not clear whether these are the only two SNPs that have an unresponsiveness to niacin or indeed have specific association with niacin unresponsiveness. The said SNPs are disclosed as ones that "…*fall within two predicted transmembrane receptor (TMR) domains…*". It is then stated that if a mutation is found when the client is screened, then it can be determined that the product (Strivectin SD) will be inactive for this individual. However, it is stated in Example 1 at page 15, lines 29-31 that to increase the power of discrimination between cosmetic products the customer can be tested with more than one SNP to provide a full spectrum of efficacy within the product. The examiner concluded that this would place an undue burden on the skilled person to find all the SNPs associated with each active ingredient present in the product and to find which are associated with a responsiveness or unresponsiveness as appropriate. Further, there is no clear teaching in Example 1 of how weights for the two said SNPs are actually calculated. In Example 2 not one specific SNP is indicated for SNP1 MMP1, it merely states that if the customer has the mutant variant of SNP1 MMP1 then the product Elemis would be recommended.

59 Further on in the description at page 16 it is stated that "…*the active ingredient is given a weight according to the various genotypes…*" where it goes on to show how weightings are applied for the compounds niacin and vitamin D (Table 4) and niacin and retinol (Table 5). It is also described that the weights are applied depending on whether the *"…level of interaction is first, second or third level…*". The Examiner stated that he could see no clear teaching as to how one would calculate a weight for each active ingredient, for those specifically exemplified never mind any further active compounds or combinations thereof. As regards each "*level of interaction*" in

Tables 4 and 5, it was not clear to the examiner how these translate into the "*weight*" numbers arrived at and how they may be applied to other compounds. Indeed, he suggested that the application of weights in these tables appeared to be arbitrary.

60 It is also argued that in claim 1, the term "…*associating each of a predetermined set of active ingredients with one or more of said single-nucleotide locations…*" has no clear meaning since there is no indication in the application as filed how any active ingredients are "associated" with any SNPs – those specifically in the examples never mind any of the myriad of possible combinations of SNPs and compounds not yet tested.

The view of the Applicant

61 In response to this, the agent, in their letter dated 9 January 2014 on behalf of the applicant, referred, in particular, to the following parts of the description as filed

> *"The weight or weights applied to a location may be dependent upon the level of interaction of an expressed gene, within which the single-nucleotide location is found, with an active ingredient. A location may be given a relatively low weight if a single-nucleotide polymorphism is present that is indicative of a function defect and may be given a relatively high weight if a single-nucleotide polymorphism is present that is indicative of a function gain." (see page 2, line 31 to page 3, line 2),*
>
> *'A degree of impact, or weight' associated to a SNP is determined by a scoring method which will be explained in more detail below. These weights are typically not binary weights but rather have a degree of granularity." (see page 7 lines 15-18)*
>
> *"Each active ingredient is given a Weight according to the various genotypes, e.g. wild type (WY), mutated (MW), and heterozygous (Het) Table 4 illustrates how the weightings are applied in the case or the active ingredient Niacin. Different weights are applied depending upon whether the level of interaction is a first, second or third level." (see page 16, line 30 to page 17, line 7)*

62 The agent argued that, in the light of the general directions given in the application and, in particular, the passages cited above — the skilled person would clearly appreciate that, to effect the invention, he or she needs to perform certain experiments (or indeed identify already published data) to identify SNPs that are relevant to the efficacy of an active ingredient (of interest), to determine the level of interaction of the SNP, and to allocate a weight based upon the level of interaction. This final step could merely involve allocating a weight of 0 to a SNP that inhibits completely an interaction, a weight of 5 to a SNP that partially functions, and a weight of 10 to a SNP that is fully functioning. While conceding that the allocation of weights may be to some extent subjective, i.e. the relative values of the weights do not need to exactly reflect the relative levels of interaction (of SNPs at particular locations), he pointed out that the objective is not to provide some exact measure of the relevance of active ingredients (to the individual) and some exact product score for available products. Rather, the objective is to allow products to be ranked in a way that indicates at a general level their relevance to the individual. This approach

represents a significant advance over prior art product selection methods which rely on user choice, questionnaire-based selection, and/or a visual analysis (e.g. of skin appearance).

63 The agent considered that the Examiners arguments that the application does not teach how the weights given for the specific, exemplary SNPs are derived, and that it does not teach how weights for other SNPs may be derived, misses the relevant point.

Analysis

64 I have already discussed the construction of the claims currently on file in the above discussion in relation to Section 1(2) of the Act. The question to be answered, in essence, is - is there sufficient disclosure in the application as filed for a person skilled in the art to carry out the invention as claimed, the key to which is the identifying step (see step (ii) above).

65 The applicant addressed me in both the skeleton argument and at the hearing on the issue of who the person skilled in the art would be and how they would be able to carry out the invention as claimed. They considered that it would be well within the capabilities of the skilled person to determine appropriate weighting values for SNPs associated with a given active ingredient and, as a precursor, to determine SNPs of interest for a given (undisclosed) active ingredient.

66 I was referred first to the skeleton argument provided by the agent on 4 June 2014 and the witness statement from Dr Emma Blamont, a Senior Research Officer with the charity Breakthrough Breast Cancer that accompanied it. I note Dr. Blamont's technical experience and accept that a person such as Dr Blamont would be likely to be the type of person that might be considered, in the context of this invention, to be a member of the skilled team involved in implementing the invention.

67 Dr. Blamont was presented with a copy of the current patent application and the official examination report dated 26 February 2013 and was asked by the agent to address herself to the three questions which I have summarised below:

> (1) Does she fully understand the principles of the method presented in the application;
> (2) Would the skilled person, presented with the teaching of the application, be able to determine "weights" to be applied to particular SNPs for a particular active agent other than those identified in the application; and
> (3) What, if any, difficulties would be encountered in determining an appropriate set of SNPs for a given active agent.

68 In answering these questions Dr Blamont stated that (i) she believes she fully understands the principles of the method presented in the application, (ii) she presented a methodology that she (and her team) would follow in order to achieve weightings to be applied to particular SNPs for a particular active agent using publicly available resources and (iii) she also presented a methodology for identification of an associated set of SNPs for a theoretical "active ingredient X" using the disciplines of biomedical text/data mining as well as bio-informatics. In

areas (ii) and (iii) she stated that she did not foresee any difficulties in the skilled person arriving at the precise kind of information required.

69 I do not propose to reproduce all the detailed answers provided by Dr Blamont in the present decisions. I found this witness statement very helpful and the answers provided to the questions she was asked clear and easy to follow. I am satisfied that the person skilled in the art would be in fact be a skilled team made up of a number of disciplines including a bio-informaticist (with expertise in searching databases and data retrieval), a geneticist, a biochemist (with expertise in metabolic/cell signalling pathways and protein chemistry in order to understand the relevance of any polymorphisms found) and, depending on the assays to be performed to determine the functional relevance of the SNPs, one or more technicians with experience in the relevant assay(s) to be used.

70 I am also satisfied, that as Dr Blamont outlined, it would be possible for the skilled team to ascertain the weights for a given set of SNPs associated with a cosmetic active ingredient.

71 I note in particular that Dr Blamont commented that "*the SNP "weighting" system used by the authors is really a method to score SNPs and then consider the effect of combining levels of interactions in response to a particular ingredient. Normal is always fixed at the value of 10 and values of "greater" or "worse" function than normal are assigned in accordance with this. Such systems are commonly used in research laboratories — so would not impose an undue burden upon the skilled person(s) compared to common research practices especially when undertaken as part of a skilled team."*

72 I also satisfied that, following the explanation provided by Dr Blamont of how such a skilled team would be able to carry out such work, the identification of the SNPs which would have functional consequences for the mechanism of action of a new cosmetically active ingredient (which she refers to as active ingredient X) does not represent an undue burden or require inventive skill. Various databases are available which could be used to identify the targets for active ingredient X such as the membrane bound receptors upon which "X" acts and the downstream signalling molecules or enzymes as well as the genes which code for these receptors or enzymes. In addition, databases of SNPs and their locations on genes are available so that SNPs on the relevant genes coding for targets of active ingredient X can be identified and then assessed for their impact factor. If the SNP function is not already known, the biochemist in the team with knowledge of protein chemistry would likely be able to predict or model the function of the SNP.

73 During the hearing, Dr Lind and Dr Nedjai-Hunault made the point that the work that would need to be done to identify SNPs and associate them with particular compounds is one that the skilled person could readily perform and would not be unduly burdensome or require inventive skill. It was clearly understood that things would be easier for known active cosmetic ingredients when compared to new active cosmetic ingredients being developed because the genes that code for the biochemical pathways that involve the former type of ingredients will be known, for example through various gene mapping projects and databases that are known in the art and, thus, the SNPs can be worked out. One would also need an understanding of the biological pathways involved with the SNPs in question which is

something the skilled person would be able to do, again without any inventive skill. The application of weights to these associations whilst seemingly arbitrary is constant across the testing model in the method – i.e., the values given are not so important, it is the relationship between the values that matter here.

74 Having reviewed the witness statement and in light of the arguments presented in the skeleton argument and at the hearing, I am persuaded that the disclosure in the application as filed is presented in enough detail for the skilled person to carry out the invention. It would therefore appear that the requirements for sufficiency in *American Home Products*[13] and *DSM*[14] with regard to the burdens of experimentation, expense and labour to perform the invention are not undue in this instance. In *American Home Products*, the Court of Appeal distinguished between a sufficient description, which requires the skilled person to use his skill in order to perform the invention, and an insufficient description which requires the skilled person to have to go to the expense and labour of trying to ascertain which of the products encompassed by the claim actually have the required properties.

75 In *Eli Lilly*[10], Kitchin J held that the specification must be sufficient to allow the invention to be performed without undue burden, having regard to the fact that the specification should explain to the skilled person how the invention can be performed. It was admitted therein that whether the burden is undue must be sensitive to the nature of the invention, the abilities of the skilled person and the art in which the invention has been made. It is clear that the working the present invention would not be the job of a single person. As referred to above, it would be the task of a multi-disciplinary team that includes for example an expert in bio-informatics with expertise in searching databases and data retrieval, a geneticist and a biochemist with expertise in metabolic/cell signalling and protein chemistry to understand the relevance of polymorphisms found. It is therefore appreciated that the work involved in identifying SNPs and apportioning weights to the interaction of active cosmetic compounds with these SNPs would not be unsubstantial but it would not be an impossible or undue burden to those skilled in the art.

Relevance of the Auxiliary request

76 The set of amended claims referred to as the auxiliary request and filed on 4 June 2014 prior to the hearing, proposes to introduce into claim 1 currently on file the feature that each SNP location that is tested for is located within a gene that, when expressed, interacts with one or more of the active ingredients. In my view such an amendment would, echoing the finding in the *Eli Lilly* judgment referred to already, make it easier for the skilled person to know how the invention is to be performed. The applicant may want to consider formally submitting these amended claims for consideration by the examiner. However, this is a matter for them to decide but it would be helpful for them to do so as soon as possible so they can be dealt with as part of the outstanding issues remaining on this application.

Conclusion

[13] *American Home Products Corp. v Novartis Pharmaceuticals UK Ltd [2001] RPC 8*
[14] *DSM NV's patent [2002] RPC 35*

77 Taking account of all of the above, I consider that the present application, as claimed in claims 1-11 currently on file, does not fall within the exclusions of Section 1(2) of the Act. Thus I consider that this application meets the requirements of Section 1(1)(d) of the Act

78 Furthermore, I am also satisfied that the application fulfils the requirements of Section 14(3) of the Act to "*disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art."*

79 I note that, in addition to the proposed amendment, there are outstanding novelty, inventive step and support/clarity matters concerning this application that still remain to be resolved. I remit the case back to the examiner for further processing under Section 18 of the Act.

Appeal

80 Any appeal must be lodged within 28 days

Dr L CULLEN
Deputy Director, acting for the Comptroller