Patents Act 1977 **Opinion Number** **30/18**

OPINION UNDER SECTION 74A

Patent	EP 3162841 B1
Proprietor(s)	PEP Licensing Limited
Exclusive Licensee	
Requester	T.S. Shankar
Observer(s)	PEP Licensing Limited
Date Opinion issued	08 February 2019

The request

1. The comptroller has been requested by T.S.Shankar ("the requester") to issue an opinion as to whether the claims of EP(UK)3162841 B1 ("the patent") lack novelty in light of documents D1-D23 provided by the requester, and also whether the specification discloses the invention clearly and completely enough for it to be performed by a person skilled in the art. The request was received from the requester on 16 November 2018. It was accompanied by a statement explaining the request as well copies of the documents listed below:

D1: Advanced Enzyme Science Limited, Material Safety Data Sheet – Enzymoplast® ENZO0001 http://www.enzymoplast.com/AESL_ENZO0001_MSDS_April2013.pdf

D2: Advanced Enzyme Science Limited, Material Safety Data Sheet – Enzymoplast® ENZO0900 http://www.enzymoplast.com/AESL_ENZO0900_MSDS_April2013.pdf

D3: US6630422 B1

D4: EP1119378 B1

D5: An analysis of composting as an Environmental Remediation Technology https://www.epc.gov/sites/production/files/2015-09/documents/analpt_all.pdf

D6: AESL WRITTEN EVIDENCE – UK PARLIAMENT http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/environmental-audit-committee/plastic-bags/written/5381.html

D7: Enzymoplast Product Launch 7 February 2014 https://www.britishplastics.co.uk/uk-firm-suggests-carrier-bags-can-be-both-recyclable-and-bio/

D8: REPSOL and AESL Product Launch 16 June 2015
https://www.plasticstoday.com/content/are-repsol-s-biodegradable-polyolefins-real-thing/20755789322402

D9: AESL Ownership
https://beta.companieshouse.gov.uk/company/08063441/officers

D10: Narinder Pal Bharaj – Personal Appointments
https://beta.companieshouse.gov.uk/officers/Ci-Z4r-VYfxkxgPXRqdNAxa1P_k/appointments

D11: Enzymoplast product launch video (06.12.2011)
https://www.youtube.com/watch?v=kUvFpPz718M

D12: Biotec Bags – CNN Interview video (13.09.2013)
https://edition.cnn.com/videos/world/2013/09/13/kapur-iexchange-biotec-bags-biodegradable.com

D13A and D13B: Bioplast Technologies India Private Limited – EN1342 Results

D14: Bioplast Technologies India Private Limited – Authorisation letter to Biotec Bags, India

D15: Ravi Industries – Authorisation letter to Biotec Bags, India

D16: Bio-degradable plastic hits the market – Times of India 16 February 2009
https://timesofindia.indiatimes.com/city/chennai/Bio-degradable-plastic-hits-the-market/articleshow/4133344.cms

D17A, D17B, D17C and D17D: Invoice copies (shipping data by M/s. Bioplastic Technologies India on behalf of Advanced Enzyme Sciences Limited (Enzymoplast))

D18: Bioplast Technologies, India and Advanced Enzyme Science Private Limited, AESL (Enzymoplast) – Authorisation letter to Biotec Bags

D19: Bioplast Technologies and Advanced Enzyme Sciences Private Limited, AESL (Enzymoplast) – Authorisation letter to M/s. Nutrino Exports

D20: Company Name Change – Enzymoplast Ltd to Advanced Enzyme Sciences Private Limited AESL (14 August 2012)
https://beta.companieshouse.gov.uk/company/08063441/filing-history

D21: Bioplast Technologies India – Company profile
https://www.indiamart.com/bioplasticindia/aboutus.html

D22A and D22B: GB201121663 D0

D23A to D23H: Invoice copies to M/s. Biotec Bags India Private Limited for the supply of biodegradable masterbatches by M/s. Ravi Industries, India and M/s. Bioplast Technologies India

Observations and observations in reply

2. Observations were received from the proprietor's representative on 24 December 2018, which were accompanied by copies of the documents listed below:

   Annex 1, copy of ISO 14855;

   Annex 2 declaration by Narinder Bharj; and

   D22C, UKIPO register extract.

3. Observations in reply were submitted by the requester on 10 January 2019.

Matters to be considered by this opinion

4. Section 74A of the Patents Act 1977 (herein after "the Act") provides for the procedure where the controller can issue, on request, non-binding opinions of validity relating to novelty, inventive step, added matter, sufficiency and excluded matter amongst other things, and on questions of infringement. Any observations should be confined to the issues raised by the request and should not broaden the scope of the opinions by raising new issues.

5. The proprietor comments that *"The requester has mentioned combination of some of the above documents with D3, D4 and D5 would affect the patentability of the claims. The requester has alleged lack of novelty. In the patentee's opinion, however, this should be treated under inventive step. An opinion is not requested with regards to inventive step of claim 1. No specific arguments have been presented about obviousness of claim 1. Thus we believe that there is no basis for the UKIPO to consider inventive step in this opinion"*. I agree with the proprietor that there are some comments within the request, for example "*Claim 1 is therefore not novel over D1, D2 and D6 in combination with the cited articles D3 or D4 or D5"*, which would appear to relate to inventive step rather than novelty.

6. In my view no clear arguments in relation to inventive step have been put forward in the request. Furthermore, I do not believe that the proprietor has had a sufficient opportunity to respond to any inventive step considerations adequately. Inventive step will therefore not be considered in this opinion.

7. D22A and D22B were cited in support of the request. Both documents relate to an unpublished patent application filed with the UK Intellectual Property Office. As argued by the proprietor this application was withdrawn before publication and therefore was never made available to the public. As these documents do not form part of the state of the art in accordance with section 2(2) they cannot be used to determine lack of novelty. Therefore documents D22A and D22B will not be considered in this opinion.

8. The requester also relies on documents D13A and D13B which relate to test certificates of the biodegradability of a HDPE bag. The proprietor contends that these were not made publically available however this is refuted by the requester. Based on the evidence presented I am not in a position to determine whether these

documents were in fact in the public domain. However in the interests of helping the parties to resolve their dispute I will nevertheless comment on these documents.

The patent

9. The Patent entitled “A biodegradable biocompostable biodigestible plastic” was filed on 27 October 2015, and was granted on 21 March 2018. The patent remains in force in the United Kingdom.

10. The patent relates to a process for imparting biodegradability, biocompostability and biodigestability to a polyolefin plastic by adding a specific combination of ingredients to the plastic during production of the polyolefin polymer material. A key feature of the invention is that the material incorporates natural peptides, enzymes and proteins from edible sources, so as to render the non-biodegradable polyolefin polymer, such as polyethylene or polypropylene, biodegradable, biocompostable and biodigestible.

11. The plastic material is prepared by mixing at least one peptide, protein selected from vegetable or milk protein and an enzyme selected from papain and cellulase; adding a composting agent; and blending with at least one polymer in the presence of an additive at 45-300^{o}C so as to retain the essential catalytic properties of the peptide/enzyme/protein in the solid or liquid form.

12. The patent explains that the polyolefin polymer material retains the desired mechanical properties, including physical strength and structural characteristics, shelf-life and recyclable properties equal to that of the non-biodegradable polymer, and unlike photo-oxidative or oxo-degradable agents which initiate degradation of the polymer spontaneously, and thereby reduce the shelf-life of the polymer products, enzymatically initiated biodegradation, biocompostability and biodigestion processes, as utilised in the invention, begin only upon exposure to microbes in the environment as the life cycle ends. The plastic material of the invention can be used in the manufacture of products such as carrier bags, packaging/plastic films, bin liners, rubbish bas, agricultural mulch films, polymer fibres and non-woven spun materials.

13. There are fourteen claims, including two independent claims, claims 1 and 9.

14. Claim 1 reads as follows:

> *A process for the preparation of a biodegradable/biocompostable/biodigestible plastic comprising steps of:*
> - *Mixing at least one peptide, protein which is selected from vegetable and milk protein and enzyme which is selected from papain and cellulase,*
> - *Adding a composting agent,*
> - *Blending with at least one polymer in the presence of additive to obtain said plastic, wherein the polymer is a polyolefin and wherein said blending is carried out at a temperature of 45-300^{o}C so as to retain the essential catalytic properties and nature of the peptide/enzyme/protein in the solid or liquid form.*

15. Claim 9 reads as follows:

> *A biodegradable/biocompostable/biodigestible plastic comprising:*
> *a polyolefin polymer,*
> *at least one peptide, protein which is selected from vegetable and milk protein and enzyme which is selected from papain and cellulase,*
> *a composting agent, and*
> *an additive*

Novelty

16. Section 1(1)(a) of the Act reads:

> *1(1) 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;*

17. The relevant provisions in relation to novelty are found in section 2(1) and section 2(2) which read:

> *2(1) An invention shall be taken to be new if it does not form part of the state of the art.*
> *2(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, process or 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.*

18. I will begin by determining whether claims 1 and 9 are novel and, if these claims are considered to lack novelty, I will then go on to consider the dependent claims.

19. When considering validity of the claims of the patent I will first need to construe them. This means interpreting them in light of the description and drawings as instructed by section 125(1) and take account of the Protocol to Article 69 of the EPC. In doing so I must interpret the claims in context through the eyes of the person skilled in the art. Ultimately the question is what the person skilled in the art would have understood the patentee to be using the language of the claims to mean. This approach has been confirmed in the recent decisions of the High Court in Mylan v Yeda[1] and the Court of Appeal in Actavis v ICOS[2].

20. Section 125(1) of the Act states that:

> *For the purposes of this Act an invention for a Patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of protection conferred by a patent or*

[1] Generics UK Ltd (t/a Mylan) v Yeda Research and Dev. Co. Ltd & Anor [2017] EWHC 2629 (Pat)
[2] Actavis Group & Ors v ICOS Corp & Eli Lilly & Co. [2017] EWCA Civ 1671

application for a patent shall be determined accordingly.

21. The requester has not made any comments identifying the person skilled in the art. I note, in relation to inventive step, the proprietor has identified the person skilled in the art as *"a chemist in the field of biodegradable/biodigestible/biocompostable plastics. Their common general knowledge is set out in broad terms in paragraph [0006] of the patent"*. Whilst I cannot consider the inventive step arguments the statement by the proprietor regarding the skilled worker is helpful and I do not believe is contentious.

22. Therefore in my view the person skilled in the art is a chemist working in the field of biodegradable/biodigestible/biocompostable plastics. I consider that they would be aware of various types of biodegradable plastics including photodegradable, oxo-degradable, oxo-biodegradable, biodegradable, bio-photodegradable and a combination of photo- and/or oxo- and/or biodegradable plastics, and would have knowledge of the advantages and disadvantages of each type of plastic in relation to cost of manufacture, mechanical properties, including physical strength and structural characteristics, shelf-life, degradability of the plastic and impact on the environment.

23. Neither the requester nor the proprietor has made any comments in relation to the construction of claims 1 and 9 or how these claims should be interpreted. I consider that claims 1 and 9 are generally clear and straightforward to construe. I note that neither the requester nor the proprietor have given any comment regarding the feature *"adding a composting agent"*, or the interpretation of the term *"adding"*, however I believe that it is worthy of consideration.

24. I consider that the person skilled in the art would understand the term *"adding"* to mean a deliberate act, as opposed to something being intrinsically mixed, i.e. absorbed, from the surroundings. In my opinion the skilled worker would therefore understand the wording *"adding a composting agent"* to mean the act of deliberately incorporating a quantity of composting agent.

Novelty – claim 1

25. The requester submits that claim 1 is not novel in light of the prior art documents D1 or D2. To justify a finding that claim 1 of the patent lacks novelty I must find that the prior art disclosure clearly and unambiguously discloses all of the features of claim 1. Therefore I must find that the prior art disclosure not only discloses the components of the plastic composition but also discloses the process steps required in preparing the composition.

26. D1 is a material safety data sheet published by AESL (Advanced Enzyme Science Limited) for the commercial product Enzymoplast® ENZO0001. D1 discloses details of the composition including the ingredients list and CAS Registry numbers of the components. Also included is information relating to the percentage amounts of components within the ENZO0001 composition. The physical and chemical properties of the composition and the regulatory information is also disclosed.

27. The requester argues *"The composition of the claim 1 of the patent in question EP 3162841 B1 is disclosed in detail by the cited documents D1 and D2"*.

28. As acknowledged by the requester and proprietor D1 discloses that the product contains ethylene, butane and citric acid. I am satisfied that these components meet the terms of the features *"polyolefin"* and *"additive"* in claim 1.

29. I note that there is disagreement between the requester and proprietor regarding the identity of some of the components disclosed in D1. The proprietor submits that the enzyme (CAS no. 9001-73-4) is cellulase and vegetable protein A (CAS no. 73049-73-7) is meat peptone, however the requester asserts that the enzyme is papain and vegetable protein A is (Hy Soy) selected from soy bean.

30. I am in agreement with the requester that the enzyme disclosed in D1 is papain and I am satisfied that this meets the requirements of the term *"an enzyme which is selected from papain and cellulase"* defined in claim 1.

31. With regard to the identity of vegetable protein A, I agree with the proprietor that the CAS number 73049-73-7 relates to meat peptone (which is also known as HY SOY). However, I note from the Sigma-Aldrich website that this CAS number also relates to peptone from casein (i.e. milk solids). Without further information I am unable to conclusively determine the specific identity of the peptone (CAS no. 73049-73-7) used in the composition disclosed in D1 and I am therefore unable to definitively ascertain whether this component meets either of the terms *"at least one peptide"* or *"protein which is selected from vegetable and milk protein"* as required by claim 1.

32. The proprietor contends that *"The CAS no. 910719-40-2 given for vegetable protein B corresponds to no product, so that the nature of this protein has not been disclosed"*. I note that the requester has not provided any comments in relation to the identity of vegetable protein B.

33. It is an established principle that a novelty disclosure requires: prior disclosure and enablement. From the information provided in D1 I do not believe that the person skilled in the art would be able to determine the identity of vegetable protein B. It is therefore my opinion that this component of the composition has not been made available to the public and thus does not meet the requirements of a prior disclosure in the context of novelty. Thus in my view D1 does not meet the requirements of a prior disclosure with regard to either of the terms *"at least one peptide"* or *"protein which is selected from vegetable and milk protein"* defined in claim 1.

34. The requester argues *"Further the cellulose and its derivatives including carboxymethylcellulose (CMC) are widely used in this area for their biodegradability and composting characteristics and the same is disclosed in the cited documents D3, D4 and D5"*. A novelty disclosure must clearly and unambiguously disclose all of the features of the claim and cannot be supplemented with common general knowledge or information contained in other documents or sources. I can find no disclosure of carboxymethyl cellulose in D1.

35. The proprietor contends that *"D1 at least does not disclose a composting agent"*.

36. The requester argues *"The document D1 discloses the composition to be unstable when exposed to moisture. Implicitly, once water and oxygen are mixed in, these ingredients act as composting agents. Thus implicitly D1 discloses composting agent"*. However I am not convinced by the requester's argument. As discussed

above I have construed the term *"adding"* to mean a deliberate act as opposed to being intrinsically mixed from the surroundings. Thus I do not believe that these elements have been *"added"* in the context of claim 1 as construed.

37. The requester further submits that *"The vegetable proteins mentioned in the composition can also perform the role of a composting agent"*. Claim 1 requires that the composition comprises at least one peptide, protein selected from vegetable protein and a composting agent. I consider that the person skilled in the art would understand from the wording of claim 1 that the peptide, protein and composting agent are present as distinct components. Notwithstanding that I have been unable to determined identity of vegetable protein A and vegetable protein B, D1 fails to disclose a further distinct composting agent. Moreover, no evidence has been submitted to demonstrate that the vegetable proteins A and B are composting agents.

38. The requester also argues *"there is no novel component attached to the manufacturing parameters as disclosed in claim 1"*.

39. The proprietor contends that *"The document* [D1] *also does not disclose blending at 45-300°C"*.

40. I am in agreement with the proprietor's view. I can find no disclosure of the step of blending a peptide/enzyme/protein composition with an added composting agent, to a polyolefin in the presence of an additive at a temperature of 45-300°C.

41. The requester argues that *"D1 discloses a melt flow index (MFI) at a temperature of 190°C. Thus D1, implicitly discloses processing of D1's product to be conducted at 190°C. Absent any hint to the contrary in D1, the skilled person understands D1 to imply typical extruder conditions…for example, a temperature of from 150 to 230°C"*.

42. As acknowledged by the requester D1 discloses that the Enzymoplast® product is a co-polymer used in manufacturing polyethylene films. Whilst I accept the requester's submission that the melt flow temperature of 190°C indicates the temperature at which the co-polymer is to be processed i.e. during an extrusion process, I am not convinced of the requester's assertion that this discloses the step of blending a peptide/enzyme/protein composition with an added composting agent, to a polyolefin in the presence of an additive at a temperature of 45-300°C.

43. In my opinion there is no disclosure in D1 of the preparation of the polymer. I can find no disclosure outlining the process steps necessary to manufacture the Enzymoplast® ENZO0001 polymer, or indeed any disclosure relating to the specific process steps as defined by claim 1. Furthermore, I can find no disclosure outlining how and in what order the components should be combined in order to prepare the ENZO0001 polymer.

44. Accordingly, it is my opinion that D1 is silent with regards to the feature of a composting agent and the process steps as required by claim 1. Furthermore, in the absence of any information regarding the identity of vegetable protein B, I do not consider that this component of the composition has been made available to the public and thus does not meet the requirements of a prior disclosure.

45. I therefore consider that claim 1 is novel over D1.

46. D2 is a material safety data sheet published by AESL (Advanced Enzyme Science Limited) for the commercial product Enzymoplast® ENZO0900. D2 discloses details of the composition including the ingredients list and CAS Registry numbers of the components. Also included is information relating to the percentage amounts of components within the ENZO0900 composition. The physical and chemical properties of the composition and regulatory information is also disclosed.

47. The composition details disclosed in D2 are essentially the same as those for D1. The only difference being the enzyme used and the disclosure of yeast in D2. The conclusions I have reached in relation to D1, as discussed above, also apply to D2, and will not be repeated here.

48. I note that both the requester and the proprietor assert that the enzyme (CAS no. 9012-54-8) disclosed in D2 is papain. However, I consider that CAS number 9012-54-8 relates to cellulase. I am satisfied that this meets the requirements of the term *"an enzyme which is selected from papain and cellulase"* as required by claim 1.

49. The proprietor contends that *"D2 at least does not disclose a composting agent"*.

50. The requester argues *"D2 discloses yeast as a component (D2, Section 2): "Yeast: CAS no. 8013-01-2". It is common knowledge that in a biodegradation process, yeast acts as a composting agent. Thus, D2 discloses a composting agent of claim 1"*.

51. No evidence has been provided to demonstrate that yeast functions as a composting agent. Moreover, I consider that D2 does not clearly and unambiguously disclose that yeast is present. Whilst I acknowledge that yeast is listed as one of the components it is omitted from the composition information table and, as highlighted by the proprietor, the percentages disclosed do not allow for the inclusion of yeast as the sum of LLDP+enzyme+vegetable protein A+vegetable protein B+citric acid is 100%. Therefore from the information provided I do not believe that there is sufficient evidence to allow me to conclusively determine whether yeast is present within the composition disclosed and that yeast is a composting agent.

52. Accordingly it is my opinion that D2 is silent with regards to the feature of a composting agent and the process steps as required by claim 1. Furthermore, in the absence of any information regarding the identity of vegetable protein B in D2, I do not consider that this component of the composition has been made available to the public and thus does not meet the requirements of a prior disclosure.

53. I therefore consider that claim 1 is novel over D2.

54. The requester further submits that claim 1 lacks novelty through dissemination of technology and prior use as the product defined by claim 1 was commercially marketed before the filing date of the patent as shown in documents D6 to D23. The basis of the requester's argument relies on the marketing and supply of the products ENZO0001 and ENZO0900 as disclosed in D1 and D2.

55. The proprietor argues *"whilst some of the evidence refers to ENZO products before*

the filing date of the patent, no evidence is provided that these products have all the features of claim 1" which I am in agreement with. As I have discussed above I do not consider that D1 or D2 disclose the composition or process method as required by claim 1. Thus in my opinion claim 1 does not lack novelty through dissemination of technology and prior use.

56. I therefore consider that claim 1 is novel over the documents presented.

Novelty – claim 9

57. The requester also submits that claim 9 is not novel in light of documents D1 or D2. To justify a finding that claim 9 of the patent lacks novelty I must find that the prior art disclosure clearly and unambiguously discloses all of the features of claim 9. That is I must find that the prior art disclosure discloses all of the components of the plastic composition.

58. The reasoning I have given above in relation to the novelty of claim 1 is equally applicable to claim 9.

59. I therefore consider that claim 9 is novel over D1 and D2.

60. The requester submits that claim 9 lacks novelty through dissemination of technology and prior use as the product as defined in claim 9 was commercially marketed before the filing date of the patent as shown in documents D6 to D23. I note that the basis of the requester's argument relies on the marketing and supply of the products ENZO0001 and ENZO0900 as disclosed in D1 and D2.

61. As I have discussed above I do not consider that D1 or D2 disclose the composition as defined by claim 9. Thus in my opinion claim 9 does not lack novelty through dissemination of technology and prior use.

62. I therefore consider that claim 9 is novel over the documents presented.

63. As I consider claims 1 and 9 be novel, I do not need to consider dependent claims 2-8 and 10-14 further.

Sufficiency

64. The requester submits that the specification does not disclose the invention clearly and completely enough for it to be performed by a person skilled in the art. Section 14(3) of the Act reads:

> *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 the person skilled in the art.*

65. It has been established that the reasoning used to assess whether an application satisfies section 14(3) is that as set out in the relevant principles of Eli Lilly v Human

Genome Sciences[3], that is:

> *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 those:*
> *(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;*
> *(iv) The sufficiency of the disclosure must be assessed on the basis of the specification as a whole including the description and 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*

66. The Manual of Patent Practice explains at paragraph 14.60 that:

> *The purpose of the requirements imposed by s. 14(3) and s. 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 (Zipher Ltd v Markem Systems Ltd [2009] FSR 1). Thus, all consideration of sufficiency in essence deals with the extent to which the applicant has provided an enabling disclosure for their invention (see also 2.10 and 72.03).*

67. In Zipher Ltd v Markem Systems[4], the objection to classical sufficiency is summed up as follows:

> *Classical insufficiency arises where the express teaching of the patent does not enable the skilled addressee to perform the invention. This type of insufficiency requires an assessment…of the steps to which it would be necessary for the skilled reader or team to take in following the teaching of the specification and in order to arrive within the claim. Plainly the steps should not include inventive ones. But a patent can also be found insufficient if the steps can be characterised as prolonged research, enquiry or experiment.*

68. The requester has submitted arguments asserting that the specification does not provide any valid documentary evidence or certificates from appropriate regulatory authorities to support that the biodegradability of the plastic material conforms to biodegradability standards and testing procedures.

69. The proprietor contends that *"The allegations of the requester are not that the skilled reader would be unable to carry out the invention, but instead that the patent does*

[3] Eli Lilly v Human Genome Sciences [2008] RPC 29
[4] Zipher Ltd v Markem Systems Ltd [2009] FSR 1

not substantiate the allegation that its compositions conform with various biodegradability/eco-toxicity standards".

70. I agree with the proprietor's comments that providing documentary evidence or certification from appropriate regulatory bodies to substantiate compliance of products with industry standards is not a requirement in patent law. However it is a requirement under section 14(3) that the specification must provide sufficient disclosure of the invention to allow the person skilled in the art to obtain the product claimed. I therefore consider that the specification must provide enough information to enable the skilled worker to produce the polymer having the biodegradability properties as evidenced in figure 5, without undue burden, i.e. without prolonged research, enquiry or experimentation, and without exercising any inventive ingenuity.

71. The requester argues that the patent *"fails to disclose certain aspects of the invention in a manner which is clear and complete enough for the invention to be performed by the person skilled in the art"*. I will consider each of these aspects presented by the requester.

72. The requester submits *"1. The details on the composition range was not disclosed anywhere in the patent and hence the request for documentary evidences were made"*.

73. I consider that the skilled worker would be aware that the amounts or ranges of components used during the preparation of the composition would be essential to the structural integrity and chemical characteristics of the final biodegradable/biocompostable/biodigestible plastic produced. As highlighted in paragraph [0035] of the patent *"Speed of degradation is generally affected by…the amount of peptide/enzyme/protein composition"*. However I can find no information within the patent to enable the skilled person to determine the amounts or ranges of components to use. Furthermore, even with the benefit of their common general knowledge, I do not believe that the skilled person would be able to determine a suitable starting point when seeking to ascertain what amounts of peptide, enzyme, protein, compositing agent, additive and polyolefin, to use without significant experimentation and trial and error.

74. The requester further contends that *"2. No sufficient disclosure on the working conditions and process steps in the claimed invention. 3. …The patent itself fails to disclose how to retain catalytic properties and nature of the peptide/enzyme/protein at temperatures 100^{o}C…"*.

75. I consider that the skilled person would be aware that proteins are temperature sensitive and are denatured at high temperatures in the order of ~100^{o}C and above. The method of claim 1 includes the desired property *"so as to retain the essential catalytic properties and nature of the peptide/enzyme/protein in the solid or liquid form"* however I can find no teaching within the patent as to how this may be achieved. I consider that the skilled person would be aware that blending the peptide/enzyme/protein/ composition, with added composting agent, with the polyolefin and additive at temperatures above ~100^{o}C would cause inactivation of the enzyme, especially if the peptide/enzyme/protein composition and composting agent were blended with molten polyolefin/additive, i.e. at a temperature of ~120^{o}C. The skilled person would therefore look to the teaching of the patent in order to

determine how to perform the blending step in order to prevent inactivation of the enzyme. However I can find no further information in relation to how the blending step is conducted to prevent inactivation of the enzyme at blending temperatures exceeding 100^{o}C. Furthermore, even with the benefit of their common general knowledge, I do not believe that the person skilled in the art would be able to determine the necessary steps required to prevent inactivation of the enzyme during the blending process.

76. I am therefore in agreement with the requester that the specification does not provide adequate information regarding the working conditions and process steps to enable the skilled person to perform the invention as defined in claim 1.

77. Furthermore, as I consider that the process of claim 1 is insufficient the biodegradable/biocompatible/biodigestible plastic as defined in claim 9 is also insufficient as the person skilled in the art would not be able to produce the product claimed.

78. In light of the above, I do not consider that the patent discloses the invention clearly and completely enough for it to be performed by a person skilled in the art and thus claims 1-14 do not meet the requirements of section 14(3) of the Act.

Opinion

79. On the basis of the evidence submitted and arguments put forward I am of the opinion that claims 1-14 are novel.

80. It is also my opinion that, based on the arguments made, the patent does not disclose the invention clearly and completely enough for it to be performed by a person skilled in the art and thus does not meet the requirements of section 14(3) of the Act, consequently claims 1-14 lack sufficiency.

Application for review

81. Under 74B and rule 98, the proprietor may, within three months of the date of issue of this opinion, apply to the comptroller for a review of the opinion.

Natalie Cole
Examiner

NOTE

This opinion is not based on the outcome of fully litigated proceedings. Rather, it is based on whatever material the persons requesting the opinion and filing observations have chosen to put before the Office.