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Indian Pharmaceutical Alliance

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April 3, 2008

By Courier

→ The Controller General of Patents, Designs & Trade Marks
Office of the Controller General of Patents, Designs & Trade Marks
Bhoudhik Sampada Bhavan, Near Antop Hill Head Post Office
S.M. Road, Antop Hill
Mumbai 400 037

Dear Sir,

Draft Manual of Patent Practice and Procedure

In terms of notification to submit suggestions on the Draft Manual of Patent Practice and Procedure, the Indian Pharmaceutical Alliance (IPA) is pleased to submit its views on the Draft.

The Indian Pharmaceutical Alliance (IPA) represents research based national pharmaceutical companies. It consists of the following Members:

Alembic Ltd	Micro Labs Ltd
Cadila Healthcare Ltd	Ranbaxy Laboratories Ltd
Cadila Pharmaceuticals Ltd	Sun Pharmaceuticals Industries Ltd
Dr Reddy's Laboratories Ltd	Torrent Pharmaceuticals Ltd
Emcure Pharmaceuticals Ltd	Unichem Laboratories Ltd
Glenmark Pharmaceuticals Ltd	USV Limited
Intas Pharmaceuticals Ltd	Wockhardt Limited
Lupin Limited	

Collectively, their R&D spend at over Rs 2,100 cr in the year ended March 2006 accounted for 90 per cent of the total private sector spending in pharmaceutical research and development.

Should you need further clarification or justification for the changes suggested herein, we will be too happy to discuss the same with you.

Thanking you,

Yours truly,
For Indian Pharmaceutical Alliance

D G Shah
D G Shah
Secretary General

Encl: a/a

Cc: Mr T C James
Deputy Secretary to the Government of India
Deptt. of Industrial Policy & Promotion
Ministry of Commerce & Industry
Udyog Bhavan, New Delhi 110 011

SUGGESTED CHANGES IN DRAFT PATENT MANUAL 2008

Sr. No.	Clause / Page No.	Existing Paragraph	Suggested Changes	Explanation for suggested changes
1.	3.2.1 P. 21	CHAPTER III PATENTABLE SUBJECT MATTER 3.2 Novelty of Invention 3.2.1 General Principle: An invention is considered new (novel) if it has not been anticipated by publication in any document any where in the world or used in the country or prior claimed in an application for patent in India or form part of the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere before the date of filing of patent application or date of priority, that is, the subject matter has not fallen in the public domain or that it does not form part of the state of the art.	CHAPTER III PATENTABLE SUBJECT MATTER 3.2 Novelty of Invention 3.2.1 General Principle: An invention is considered new (novel) if it has not been anticipated by publication in any document any where in the world or used in the country or prior claimed in an application for patent in India or form part of the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere before the date of filing of patent application or date of priority, that is, the subject matter has not fallen in the public domain or that it does not form part of the state of the art. Publication in any prior document includes, oral, written, printed in paper or electronic form, or any other form. When publication is in print form especially in electronic form then following criteria is to be met: 1. Date of publication must be ensured. 2. It should be accessible to the public. 3. It should be reproducible. <i>(Amazon.com v. Barnesandnoble.com)</i>	1. Replace the entire text in the Existing Paragraph with the Suggested Changes Paragraph. 2. The text in bold letters in the Suggested Changes Paragraph is the additional / suggested text. 3. With the surge in the use of internet/online databases in today's global economy, considering electronic publication as a prior art under a defined criteria would be instrumental in granting only valid patents.

Sr. No.	Clause / Page No.	Existing Paragraph	Suggested Changes	Explanation for suggested changes
	3.6.1 P 28	3.2.2 Although the term 'state of the art' has not been ... 3.6.1 : Prior public use of the invention in India.....	3.2.2 Although the term 'state of the art' has not been ... 3.6.1: Prior public use of the invention in India or anywhere else in the world	4. Section 2 (1) 1 defines 'new invention' under the concept of universal novelty, and requires that the invention not have been used in India or anywhere in the world before the date of filing of the patent.
2.	Sec. 3 P. 54	Section 3 What are not inventions.- <i>d) the mere discovery of a new form...</i> <i>(d) a substance obtained by...</i> <i>(e) the mere arrangement...</i> <i>(f) Omitted...</i> <i>(g) a method of agriculture or horticulture;</i> <i>(h) any process for...</i> <i>(i) plants and animals in...</i>	Section 3 What are not inventions.- <i>d) the mere discovery of a new form...</i> <i>e) a substance obtained by...</i> <i>f) the mere arrangement...</i> <i>g) Omitted...</i> <i>h) a method of agriculture or horticulture;</i> <i>i) any process for...</i> <i>(j) plants and animals in...</i>	Mistake in numbering.
3.	Sec. 3(d) P. 57	4.5.1 Mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not patentable. According to the proviso to this sub-section, a known substance in its new form such as amorphous to crystalline or crystalline to amorphous or hygroscopic to dried, one isomer to other isomer, metabolite, complex, combination of plurality of forms, salts, hydrates,	4.5.1 Mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not patentable. According to the proviso to this sub-section, a known substance in its new form such as amorphous to crystalline or crystalline to amorphous or hygroscopic to dried, or crystalline to crystalline having different crystalline structure or vice versa , one isomer to other	1. Replace the entire text in the Existing Paragraph with the Suggested Changes Paragraph. 2. The suggested text gives more elaborate explanation on Sec. 3(d) and would facilitate the readers in having a clear idea w.r.t.

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		polymorphs, esters, ethers, or in new particle size, shall be considered same as of known substances unless such new forms significantly differ in the properties with regard to efficacy.	isomer, metabolite, complex, combination of plurality of forms, salts, hydrates, polymorphs, esters, ethers, or in new particle size, shall be considered same as of known substances unless such new forms significantly differ in the properties with regard to efficacy. For an invention in essence directed to a new form of known substance being claimed as a composition for example comprising a carrier or an excipient and the new form of a known substance, the specification will be examined to determine if the composition claim is merely the presentation or conversion of a claim on the new form of the known substance to a composition claim. Such claim will not be patentable unless the new form of the known substance itself is patentable in view of significant improvement in efficacy. 4.5.1.1 The term 'efficacy' has not been defined in the Patents Act. "Efficacy" means the ability of a drug or substance to produce the intended therapeutic effect. 4.5.1.2 Reference to the term 'property' of a known substance in pharmaceutical field refers to the physicochemical properties of the drug such as the solubility of the drug in	3(d) which is an integral part of Patents Act. 3. The text in bold letters in the Suggested Changes Paragraph is the additional / suggested text. 4. Points 4.5.1.1 and 4.5.1.2 are the additional paragraphs. 5. Explanation for 4.5.1.1 - An attempt has been made to define the term 'efficacy' and property as it would help to bring more clarity for non patentable inventions w.r.t efficacy/ property. 6. Section 3 (d) requirement can not be escaped by colorable claim language alterations.

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			aqueous and other media, impurities, particle size, stability, bioavailability, interactions between the drug and excipients etc.	
4.	Sec. 3(d) P. 58	4.5.3. The examiner makes comparison with regard to properties or enhancement of efficacy between the known substance and the new form of known substance. In case the new form is further converted into another new form, the comparison is made between the already existing form and another new form but not between the base compound and another new form.	4.5.3. The examiner makes comparison with regard to properties or enhancement of efficacy between the known substance and the new form of known substance. In case the new form is further converted into another new form, the appropriate comparison is made between the best known form having higher efficacy and another new form. Thus it should be between base compound or the known form having higher efficacy as the case may be and another new form but not between placebo and another new form.	The suggested paragraph would enable the inventor which all comparative efficacy data is to be generated. Replace the entire text in the Existing Paragraph with the Suggested Changes Paragraph.
5.	Sec. 3(d) P. 58/61	4.5.5 The efficacy need not be quantified in terms of numerical value to determine whether the product is efficacious because it is not possible to have a standard numerical value for efficacy for all products including pharmaceutical products. 4.5.7 (ix) no examples for combination.	4.5.5 The efficacy need not only be quantified in terms of numerical value to determine whether the product is efficacious because it is not always possible to have a standard numerical value for efficacy for all products including pharmaceutical products. (See also 4.5.6) 4.5.7 (ix): Combination of known active substances in known or new forms that are substantially additive in effect are not patentable unless shown to possess significant or surprisingly improved efficacy over the expected additive effect. Combination of known active	1. The text in bold letters in the Suggested Changes Paragraph is the additional / suggested text. 2. The reason for including term like only/always so as to justify some cases wherein numerical values may also quantify the efficacy. 3. The text '(See also 4.5.6)' need to be included

Sr. No.	Clause / Page No.	Existing Paragraph	Suggested Changes	Explanation for suggested changes
			substances in known or new forms even if they possess significant or surprisingly improved efficacy over the expected additive effect are not patentable if they were within the grasp of a medicinal practitioner ie they were available for co-prescription by a medicinal practitioner who could have written a co-prescription containing the known substances	since it is in continuation of the explanation of efficacy. 4. Examples of section 3 (d) should include example of "combinations".
6.	Sec. 3(e) P. 63	4.6.3 However, an admixture resulting into synergistic properties of a mixture is not considered as a mere admixture e.g. soap, detergent, lubricants and polymer composition etc.	4.6.3 However, an admixture resulting into synergistic properties of a mixture is not considered as a mere admixture e.g. soap, detergent, lubricants and polymer composition etc. 4.6.3.1 Definition of Synergy: The term 'synergy' has not been defined in the Patents Act. However, in general terms, synergy refers to the phenomenon in which two or more agents acting together produce an effect greater than the normal sum of the effect, which can be produced by individual agent. Synergy should be taken into consideration with respect to a positive effect. 4.6.3.2 In the case of a combination of two or more drugs, it can be patentable only if there is significant increase in the efficacy as compared to the sum of the efficacy of the individual drugs. ix) In general...	1. Replace the entire text in the Existing Paragraph with the Suggested Changes Paragraph. 2. An attempt has been made to define the term 'synergy' as it would help to bring more clarity for non patentable inventions w.r.t mere admixture. 3. Explanation for suggestion in Point 4.3.6.2: Since combination falls under section 3(d), a combination cannot be patented if it shows only synergistic effect; it has to bring about significant increase in efficacy. 4. The text in bold letters in the Suggested Changes

Sr. No.	Clause / Page No.	Existing Paragraph	Suggested Changes	Explanation for suggested changes
				Paragraph is the additional / suggested text.
7.	P.143	6.1.5: Particulars of Publication: c) Publication of Patent application includes information on the following parameters as may be applicable to a particular case: a) Number of application b) Date of filing of application c) Title of invention d) Publication Date e) International Patent Classification f) Name and address of the applicant g) Name of the inventor(s) h) Priority details like document number, date, country, PCT application number and date etc. i) Patent of addition to / Divisional application to: along with filing date of the parent application j) Abstract of the invention including drawing (if any)	6.1.5: Particulars of Publication c) Publication of Patent application includes information on the following parameters as may be applicable to a particular case. a) Number of application b) Date of filing of application c) Title of invention d) Publication Date e) International Patent Classification f) Name and address of the applicant g) Name of the inventor(s) h) Priority details like document number, date, country, PCT application number and date etc. i) Patent of addition to / Divisional application to: along with filing date of the parent application j) Abstract of the invention including k) No. of Pages Note: However, Clause a, b, f and j are mandatory under section 11A.	1. Please include our suggestions written in "bold" because as per sec 11A it is mandatory. (GSK v. Controller of Patents, Delhi High court) 2. No. of pages of the patent if included in the publication details would facilitate in procuring the specifications from patent office. (Required to make payment)
8.	Sec. 25 P. 177	CHAPTER VII OPPOSITION PROCEEDINGS TO GRANT OF PATENT 7.1.1 a) Wrongfully obtaining No explanation is given.	CHAPTER VII OPPOSITION PROCEEDINGS TO GRANT OF PATENTS (Sec. 25-28) 7.1.1 a) Wrongful Obtaining (Section 25) i) Meaning of "Obtained the invention" –	No explanation provided for this ground/s. Add the entire text in the Existing Paragraph with the Suggested Changes Paragraph.

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Sr. No.	Clause / Page No.	Existing Paragraph	Suggested Changes	Explanation for suggested changes
			“Obtained the invention” has been interpreted to mean ‘obtained the invention which is purported to be patented’, meaning thereby to refer to the identity of the invention, not the right of the person from whom it was obtained to be regarded as the true and first inventor. A company may have a sufficient interest in an invention as to entitle it to oppose the grant under Sec. 25. Where the ground of objection is based on Sec. 25(1)(a), it is not essential that the alleged true and first inventor must join in the opposition. The question of obtaining involves deciding first whose invention it was at the time when it is alleged that the obtaining took place, next whether the invention, assuming it was the opponent’s invention, came from the opponents to the applicants. <u>ii) Patents and Confidential Information –</u> Where information relating to an invention is wrongfully obtained, i.e., in breach of confidentiality, the same may entitle an aggrieved person to prefer a suit for misuse of confidential information. Even if the invention is not covered by a patent, the information disclosing the invention can still confer a right to the inventor if the same is disclosed in confidence.	

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			iii) <u>Employee's Invention</u> – Where any invention is made by an employee during the term of employment with the employer, and the employee has, by way of contract of employment, or otherwise, agreed to assign any invention made by him, during such term, to the employer, the employer can, in such cases, make a request to the Controller to allow the application for an invention to proceed in the name of the opponent.	
9.	Sec. 25 P. 177	7.1.1 b) Prior publication / prior claiming No Explanation is given.	7.1.1 b) Prior Publication [Section 25(1)(b)] Refer Chapter III for explanation with regard to prior publication. i) The opponent should be able to point out a clear and specific disclosure in which the invention is fairly stated. There should also be a description of the use of the invention in such disclosure. ii) <u>Meaning of 'Published'</u> : Though the expression 'published' appears in the Patents Act, it has not been defined. The scope of expression 'published' under Sec. 25(1)(b) is much wider and it includes any document published anywhere in the world. When the matter in question is distributed with the object of spreading the knowledge	No explanation provided for this ground/s. Although the draft manual includes some explanation w.r.t prior publication in chapter 3 the additional explanation would help in providing more clarity to the grounds of opposition. Add the entire text in the Existing Paragraph with the Suggested Changes Paragraph.

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			among the interested parties, it would constitute publication. [(1927)44 RPC 294] Where documents relating to the invention were sent by the patentee to a commercial partner, it could be assumed that they had a duty of confidence to each other. [(1959) RPC 141 at 147] iii) <u>Nature of document</u>: In determining anticipation by prior publication, the nature of document is immaterial. Any written thing which is capable of being admitted as evidence will amount to a document within meaning of Sec. 25(1)(b). A document would include something in the nature of a description of the invention. The important factor for determining the admissibility of the prior publication is the availability of the information and not the manner, time, place or language in which it is available. (1) <i>Books, Collection of Documents etc.</i> – An invention disclosed in books or documents published prior to the date of the patent is sufficient to constitute anticipation. In case of disclosure of invention in books, it will not be necessary for the book to be read or referred. (2) <i>Photographs and Drawings</i> – The photographs and drawings submitted by the opponent may require experts	

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			date of the applicant's claim. The earlier claim may be the subject of a patent granted or the subject of a pending application. ii) <u>Analogy derived from selection patent</u> - Prior claiming arises where the earlier claim is broader than and includes within it the area covered by the later claim. Thus, in case of a "selection patent", the later claim will be held to be anticipation by prior claim, unless the applicant or the patentee of the later invention can show that he has selected an area from the prior broad disclosure which gives advantages beyond or different from those disclosed by the prior document. The patentee (or the applicant) must frame his specification in proper form and the court must be satisfied that there are real advantages in his selection. iii) <u>Criteria for prior claiming</u> - In order to establish prior claiming, it must be shown that the subject matter of a claim in the applicant's specification forms the subject matter of a <i>distinct claim</i> in the cited specification. It is not sufficient if the claims are merely <i>comprehended</i> in the subject matter of a claim in the cited specification. The comparison must be made between the claims in the relevant specifications. iv) <u>Prior claiming and insertion of reference</u> - The question of prior claiming can be	explanation would help in providing more clarity to the grounds of opposition. Add the entire text in the Existing Paragraph with the Suggested Changes Paragraph.

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			raised (1) during the investigation by the Examiner of Patents under Sec. 13; (2) in opposition proceedings under Sec. 25(1)(c) or Sec. 25(2)(c) and (3) in revocation proceedings or in a counter claim in the High Court under Sec. 64(1). If the Controller is satisfied that prior claiming is established, he may direct the insertion of a reference to the earlier patent unless the applicant submits a satisfactory amendment. Where a reference is directed by the Controller, the question whether the claim is fairly based on the matter disclosed in the specification under Sec. 10(5) must be tested in relation to the explicit acknowledgement of the grant of patent specified. v) <u>Validity of cited patent</u> – Where a reference is made under Sec. 19(1) on the ground of substantial risk of infringement, such reference may be deleted if the prior patent is revoked or otherwise ceases to be in force, or the relevant claim is deleted from the specification of that patent, or if the relevant claim has been held to be invalid, or not infringed by the working of the applicant's invention, in any proceeding before the Court or the Controller.	
11.	Sec. 25 P. 177	7.1.1 d) Prior public knowledge or public use in India	7.1.1 d) Prior public knowledge or public use in India [Section 25(1)(d)]	No explanation provided for this ground/s.

Sr. No.	Clause / Page No.	Existing Paragraph	Suggested Changes	Explanation for suggested changes
		No explanation is given.	i) This section is meant for protecting the interests of prior users of the invention claimed. A person who is already manufacturing a thing, or has previously manufactured it, and has put it into use cannot be stopped from doing what he has done before. ii) <u>"Publicly known or publicly used"</u> – If the product is made by a process which has been claimed by the applicant, the importation of such product into India before the priority date of the invention claimed by the applicant would amount to public knowledge or public use, except where such importation was for the purpose of reasonable trial or experiment.	Add the entire text in the Existing Paragraph with the Suggested Changes Paragraph.
12.	Sec. 25 P. 177	7.1.1 e) Obviousness and lack of inventive step No explanation is given.	7.1.1 e) Obviousness and Lack of Inventive Step [Section 25(1)(e)] The objection w.r.t lack of inventive step should be raised in light of Chapter 3, Section 3.9 (i) An application for a patent may be opposed on the ground that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published or having regard to what was used in India before the priority date of the claim.	No explanation provided for this ground/s. Although the draft manual includes some explanation w.r.t non-obviousness in chapter 3 the additional explanation would help in providing more clarity to the grounds of opposition. Add the entire text in the Existing Paragraph with the Suggested Changes Paragraph.

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			(ii) <u>Obviousness</u> – While determining the obviousness of an invention, no account is to be taken of any secret user [Sec. 25(3)]. In determining the issue of obviousness, both the Controller and the High Court are entitled to make use of their own knowledge and experience of the relevant scientific and technical background to the subject-matter of the alleged invention. [(1967) RPC 479 at 491] In opposition proceedings under Sec. 25(1)(e) and 25(2)(e), it must be shown that the invention “clearly” does not involve any inventive step while there is no such qualification under Sec. 64(1)(f), i.e. ground for revocation of a patent. Obviousness is a question of fact which must be decided objectively. In deciding this question, all the relevant circumstances <i>should be taken into account. The correct conclusion may well depend on the form and scope of the claim under consideration construed in the light of the relevant surrounding circumstances.</i> [(1970) RPC 565 at 570] Once it is conceded that there is a difference between that which has been proved to have	

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			been published and used and that which forms the subject matter of the monopoly claimed, the difference between the two, if an opposition is to be successful, must be shown clearly to have been obvious and not to have involved any inventive step [(1956) RPC 163 at 173].	
13.	Sec. 25 P. 177	7.1.1 f) Not an invention or the invention not patentable No explanation is given.	7.1.1 f) Not an Invention or the Invention Not Patentable [Section 25(1)(f)] An application for a patent may be opposed on the ground that the subject of any claim of the complete specification does not qualify for being patentable under the Patents Act. The three requisites of an invention, i.e., novelty, inventive step and industrial application contained in Sec. 2(1)(j) should be satisfied for an invention to be patentable under the Patents Act. If the invention does not satisfy the test laid down in Sec. 2(1)(j), it fails to qualify as a patentable invention under the Patents Act. Inventions not patentable under the Patents Act are enumerated in Sec. 3 and 4 of the Act.	No explanation provided for this ground/s. Add the entire text in the Existing Paragraph with the Suggested Changes Paragraph.
14.	Sec. 25 P. 177	7.1.1 g) Insufficient description of the invention No explanation is given.	7.1.1 g) Insufficiency of Description [Section 25(1)(g)] The objection under Sec 25(1) (g) for insufficient description should be analysed w.r.t sufficiency of disclosure as mention in	No explanation provided for this ground/s. Add the entire text in the Existing Paragraph with the Suggested Changes

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			chapter 5 section 5.9. The sole question under an objection of insufficiency is whether or not the description which has been given is going to be sufficient to enable a person who is reasonably skilled in the particular filed to make an embodiment of the invention which will have the features which make it fall within the objects of the invention.	Paragraph.
15.	Sec. 25 P. 177	7.1.1 h) Failure to disclose information or furnishing the false information relating to foreign filing No explanation is given. 7.1.2 vi (a) Not available	7.1.1 h) Failure to disclose information regarding foreign applications – Sec. 25(1)(h) Section 8 requires an applicant for a patent to disclose to the Controller particulars regarding any application, in respect of substantially the same invention, which he might be prosecuting in any foreign country. Failure to furnish such information is made a ground for opposing the application. It is also a ground for revocation of a patent under Sec. 64(1)(m). The controller will forward applicants statement and evidence to the opponent and	No explanation provided for this ground/s. Add the entire text in the Existing Paragraph with the Suggested Changes Paragraph. It would help in clarifying the matter if incorporated

Sr. No.	Clause / Page No.	Existing Paragraph	Suggested Changes	Explanation for suggested changes
16.	Sec. 25 P. 185	7.2.2 Proceedings under Post Grant Opposition [section 25(2)] iv. Opposition Board: On receipt of the notice of opposition under rule 55A, the Controller, by order, shall constitute an Opposition Board which will consist of three examiners as members, other than the examiner who has examined the application. The Controller shall nominate one of the	7.2.2 Proceedings under Post Grant Opposition [section 25(2)] iv. Opposition Board: On receipt of notice of opposition under Rule 55A, the Controller shall constitute Opposition Board consisting of officers from the Patent Office and refer the notice of opposition and the related documents to the Board for examination. The Opposition Board shall consist of	1. The changes suggested including at least one senior person like asst. controller in the board so as to bring justified approach and to serve the purpose of issuing quality patents. 2. The text in bold letters

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		Section 65, or by the Central Govt. under Section 66, are not appealable.	under Section 65, or by the Central Govt. under Section 66 , are not appealable.	public interest under Sec. 66 is appealable under Sec. 117B-A (2).
18.	Sec. 132 P. 327	23.1.2: Not available	The applicant for the patent" includes the designated assignee for the patent and if the designated assignee is a company then any employee of the company or its subsidiary or any group company which employee has been entrusted with the task of patent prosecution	Required in view of shortage within companies of trained technical personnel in this area who can present both the technical as well as the legal aspects of the invention to the patent office.

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