KEI TPP Briefing Note: The Evolution of the Article on Patents/Patentable Subject Matter in the Trans-Pacific Partnership Intellectual Property Chapter
August 11, 2015

The following is a comparison of the text in the TPP on Patentable Subject matter. The comparisons are from the three leaked versions of the IP Chapter, dated August 30, 2013, May 16, 2014, and May 11, 2015, and include **QQ.E.1 Patentable Subject Matter**, and **QQ.E.8-10 Additional Requirements for Patents**. We first present the text from the TRIPS and the relevant sections of the TPP in the 2013, 2014 and 2015 leaked drafts, followed by a short commentary.

Note: KEI has added some highlights in the way of background colors. Green indicates a KEI comment. Blue indicates the text is a footnote. And yellow highlights some of the sections referred to in the commentary.[1]

QQ.E.1 Patentable Subject Matter

TRIPS Agreement. 15 April 1994.	TPP IP Chapter. August 30, 2013[2]	TPP IP Chapter. May 16, 2014[3]	TPP IP Chapter. May 11, 2015[4]
Article 27: Patentable Subject Matter	**Article QQ.E.1: {Patents / Patentable Subject matter}**	**Article QQ.E.1: {Patents / Patentable Subject Matter}**	**Article QQ.E.1: {Patents / Patentable Subject matter }**
1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights	1. Subject to the provisions of paragraph 2 and 3, each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. [87] [US/AU propose; [88] CL/MY/PE/SG/VN/BN/NZ/CA/MX oppose: The Parties confirm that:	1. Subject to the provisions of paragraph 2 and 3, each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application.[54] ---	1. Subject to paragraphs 3 and 4, each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. [58] {KEI note: this is the first sentence in TRIPS 27.1. The second sentence in 27.1 was dropped.}

[1] Professor Brook Baker provided helpful comments on an earlier draft of this note.
[2] TPP Negotiation, IP Group, Intellectual Property [Rights] Chapter, 30 August, 2013. Available at: http://keionline.org/sites/default/files/Wikileaks-Aug2013-TPP-IP-chapter.pdf.
[3] TPP Negotiation, IP Group, Intellectual Property [Rights] Chapter, 16 May, 2014. Available at: https://wikileaks.org/tpp-ip2/
[4] TPP Negotiation, IP Group, Intellectual Property [Rights] Chapter, 11 May, 2015. Available at: http://keionline.org/sites/default/files/Section-E-PatentsUndisclosed-Data-TK-TTP-IP-Text-11May2015.pdf

enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. 5 For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.	(a) patents shall be available for any new uses or methods of using a known product], [US/JP propose; CL/MY/PE/SG/VN/BN/AU/NZ/CA/MX oppose: (b) a Party may not deny a patent solely on the basis that the product did not result in enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application.] [87] For purposes of this [Section] Article, a Party may deem the terms “inventive step” and “capable of industrial application” to be synonymous with the terms “non-obvious” and “useful”, respectively. In determinations regarding inventive step (or non-obviousness), each Party shall consider whether the claimed invention would have been obvious to a person skilled or having ordinary skill in the art having regard to the prior art. [88] Negotiators' Note: JP is considering this provision.	[54] For purposes of this Section, a Party may deem the terms “inventive step” and “capable of industrial application” to be synonymous with the terms “non-obvious” and “useful”, respectively. In determinations regarding inventive step (or non-obviousness), each Party shall consider whether the claimed invention would have been obvious to a person skilled or having ordinary skill in the art having regard to the prior art.	------- [58] For purposes of this Section, a Party may deem the terms “inventive step” and “capable of industrial application” to be synonymous with the terms “nonobvious” and “useful”, respectively. In determinations regarding inventive step (or nonobviousness), each Party shall consider whether the claimed invention would have been obvious to a person skilled or having ordinary skill in the art having regard to the prior art. {KEI note, First sentence in footnote 58 in TPP is same as footnote 5 in TRIPS. Second sentence in footnote 58 is not in TRIPS.}
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.	2. Each Party may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.	2. Each Party may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature of the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.	2. [US/NZ/SG/AU/JP/CA/PE/MX/BN/VN propose; CL oppose: Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit such processes to those that do not claim the use of the product as such.] {KEI note: this language is a new formulation of 2014 provisions in QQ.e.1.2bis and QQ.e.1.4.; which in 2013 were found in QQ.e.1(a-b).

			Gone are the references to “enhanced efficacy of the known product.”}
		[US/JP propose; CL/MY/PE/SG/VN/BN/AU/NZ/CA/MX oppose: 2bis. For greater certainty, a Party may not deny a patent solely on the basis that the product did not result in an enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application.]	
3. Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.	3. [US: Consistent with paragraph 1] each Party [US propose; AU/NZ/VN/BN/CL/PE/MY/SG/CA/MX oppose: shall make patents available for inventions for the following] [NZ/CL/PE/MY/AU/VN/BN/SG/CA/MX propose: may also exclude from patentability]: (a) plants and animals, [NZ/CL/PE/MY/AU/VN/BN/SG/CA/MX propose: other than microorganisms]; [JP oppose: (b) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals [US propose; AU/SG/MY/NZ/CL/PE/VN/BN/CA/MX oppose: if they cover a method of using a machine, manufacture, or composition of matter]; [NZ/CL/PE/MY/AU/VN/BN/SG/CA/MX propose:] and (c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production.] [MX propose: (d) and the diagrams, plans, rules and methods for carrying out mental processes, playing games or doing business,	3. [US/JP/SG propose; AU/NZ/VN/BN/CL/PE/MY/CA/MX oppose: Consistent with paragraph 1, each Party shall make patents available for inventions for plants and animals.] Alt. 3: {Consistent with paragraph 1, each Party confirms that it makes available patents for plant-related inventions. [55]} --------- [55] {For greater certainty, no Party shall be required to make patents available for plant varieties that are protectable in that Party under the International Convention for the Protection of New Varieties of Plants [1991](UPOV Convention).} {Negotiator's Note: AU would prefer this footnote to be in the main text}. [Note: This formulation is premised upon the understanding that TPP Parties will make a commitment to accede to UPOV 1991].	3. Each Party may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. {KEI note, the sentence above is word for word from Article 27.2 of the TRIPS} Each Party may also exclude from patentability: diagnostic, therapeutic, and surgical methods for the treatment of humans or animals; animals other than microorganisms; and essentially biological processes for the production of plants or animals, other than nonbiological and microbiological processes. {KEI note, the sentence above is word for word from the first sentence in Article 27.3 of the TRIPS}

	and mathematical methods as such; software as such; methods to present information as such; and aesthetic creations and artistic or literary works.] [NZ/CA/SG/CL/MY propose: ALT 3. Each Party may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than nonbiological and microbiological processes. However, Parties shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.] ---		
		4. [US/AU/JP propose; CL/MY/PE/SG/VN/BN/NZ/CA/MX oppose: Consistent with paragraph 1, the Parties confirm that patents are available for [56]: (a) any new uses, or alternatively [57], new methods of using a known product.] [CA propose: Alt (a) any new use, or new method of using a known product that is not otherwise excluded from patentability by the Party.] [NZ/CA/CL/MY/VN/MX/BN/PE/AU propose: ALT 3. Each Party may also exclude from patentability:	4. [59] Each Party may also exclude from patentability plants other than microorganisms. [US/JP/AU propose; CL oppose: However, consistent with paragraph 1 and subject to paragraph 3, each Party confirms that patents are available at least for inventions that are derived from plants. [US/AU/JP propose; MY/NZ oppose: [60]]] FN4 (based on TRIPs Art. 27.3): Each Party shall provide for the protection of plant varieties either by patents or by a sui generis system or by any combination thereof. Such a sui generis system shall, that at a minimum, adopts or maintains the standards

		diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Parties shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.] [MX propose: (c) and the diagrams, plans, rules and methods for carrying out mental processes, playing games or doing business, and mathematical methods as such; software as such, methods to present information as such; and aesthetic creations and artistic or literary works.] --- [56] Negotiator's Note: US/JP reconsidering the inclusion of subparagraph (b) (provision relating to diagnostic, therapeutic and surgical methods), subject to consensus on patent landing zone. [57] Negotiator's Note: AU is still considering inclusion of “alternatively”.	regarding scope and conditions of protection, scope of rights, exceptions and duration of protection as set forth in UPOV ’91. --- [59] Negotiators’ note: CL has a substantive issue with the second part of paragraph 4, and is exploring language that explicitly allow the application of national practices in respect to this part. [60] US/AU/JP propose; MY/NZ oppose: Each Party affirms its commitment to the protection of plant varieties by, inter alia, an effective sui generis system, [CA oppose: Alt 1: consistent with UPOV ‘91] [Alt 2: through the obligation in QQ.A.8.2(c) (UPOV ‘91)]]]. {KEI Note. Paragraph QQ.E.1.4 in the TPP, including the footnotes and the negotiators notes, reflects the efforts by the US, AU and JP to expand obligations to grants patent “for inventions derived from plants.” Note also that Section A of the TPP IP Chapter includes the following obligation: Article QQ.A.8 {existing Rights and Obligations / International Agreements}[2] 2. Each party shall ratify or accede to each of the following agreements, where it is not already a Party to such agreement by the date of entry into force of this Agreement for the Party concerned.} : . .. (c) International Convention for the Protection of New Varieties of Plants (1991) (UPOV Convention); . . . }
			Negotiator’s Note: With respect to the second sentence of FN 4, Parties discussed the relationship between the UPOV ‘91 ratification

			provision in general provisions and the language of the FN. Some Parties commented that if a commitment to ratify/accede to UPOV ‘91 is agreed upon then the second sentence of the FN may not be necessary or may be necessary for an interim period only. One Party stated it is unlikely to accept the second sentence of the FN without further elaboration as to the provisions of UPOV ‘91 from which a Party may derogate. Negotiator’s Note: One Party is considering the placement of paragraph 2. Negotiator’s Note: CL has a fundamental issue with the content of paragraph 4, notwithstanding its support for the exception to patentability for plants

It is also useful to look also at the additional requirements of patents in Articles QQ.E.8-10.

Additional Requirements for Patents in QQ.E.8-10

	August 30, 2013	May 16, 2014	May 11, 2015
	Articles QQ.E.8-10:	**Articles QQ.E.8-10:**	**Articles QQ.E.8-10:**
	Article QQ.E.8: [US/AU/PE/VN propose;99 CL/MY/BN/NZ/CA/SG/MX100 oppose: Each Party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing date.] 99 Negotiators' Note: JP is considering this provision. 100 Negotiator's Note: MX/SG are willing to accept the article provided that the sentence "without undue experimentation" is deleted.	Article QQ.E.8: [US/AU/PE/VN/JP propose; CL/MY/BN/CA/SG/MX oppose: Each Party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing date.]	Article QQ.E.8: [US/AU/PE/VN/JP propose; CL/MY/BN/CA/SG/MX[75] oppose: Each Party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing date.] [75] Negotiator's Note: MX/SG are willing to accept the article provided that the sentence "without undue experimentation" is deleted. NZ can go along with consensus.
	Article QQ.E.9: [US/PE/AU propose; 101 CL/VN/MY/BN/NZ/CA/SG/MX oppose: Each Party shall provide that a claimed invention [AU oppose: is] [AU propose: shall be] sufficiently supported by its disclosure [AU oppose: if the disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention] as of the filing date.] 101 Negotiators' Note: JP is considering this provision.	Article QQ.E.9: [US/PE/AU/JP/SG/VN propose; CL/MY/BN/NZ/CA/MX70[70] oppose: Each Party shall provide that a claimed invention [AU/VN oppose: is] [AU/VN propose: shall be] sufficiently supported by its disclosure [AU/JP/SG/VN oppose: if the disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention] [JP propose; VN oppose: if the disclosure allows a person skilled in the art to extend the teaching therein to the entire scope of the claim] as of the filing date.] 70 Negotiators' Note: MX/SG are willing to accept the Article provided that the sentence "without undue experimentation" is deleted. NZ	Article QQ.E.9:[US/PE/AU/JP/SG/VN propose; CL/MY/BN/NZ/CA/MX oppose: Each Party shall provide that a claimed invention [AU/VN oppose: is] [AU/VN propose: shall be] sufficiently supported by its disclosure [AU/JP/SG/VN oppose: if the disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention] [JP propose; VN oppose: if the disclosure allows a person skilled in the art to extend the teaching therein to the entire scope of the claim] as of the filing date.]

		can go along with consensus.	
	Article QQ.E.10: [US/AU/MX propose;102 SG/CL/MY/VN/PE/BN/NZ/CA oppose: Each Party shall provide that a claimed invention is [US/AU propose: useful] [MX propose: industrially applicable] if it has a specific [MX propose: and], substantial, [MX oppose: and credible] utility.] 102 Negotiators' Note: JP is considering this provision	Article QQ.E.10: [US/AU/MX/SG propose;[71] CL/MY/VN/PE/BN/NZ/CA oppose: Each Party shall provide that a claimed invention is [US/AU/SG propose: useful] [MX propose: industrially applicable] if it has a specific [MX propose: and], substantial, [MX oppose: and credible] utility.] 71 Negotiators' Note: JP is considering this provision.	Article QQ.E.10: [US/AU/MX/SG propose; [76] CL/MY/VN/PE/BN/NZ/CA oppose: Each Party shall provide that a claimed invention is [US/AU/SG propose: useful] [MX propose: industrially applicable] if it has a specific [MX propose: and], substantial, [MX oppose: and credible] utility.] 76 Negotiators' Note: JP is considering this provision.

KEI Commentary on Article QQ.E.1.

The rules for patentability in Article QQ.E.1 of the May 11, 2015 version of the text are considerably shorter and less ambitious in terms of norm-setting than the 2013 and 2014 version, and more closely follow the WTO TRIPS agreement text from 1994, although with notable changes and one particularly consequential and controversial addition in QQ.E.1.2.

Consistent through each draft is text that "each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application -- the requirements of Article 27.1 of the WTO TRIPS Agreement. There are also provisions which address the exclusions from patentability in Article 27.2 and 27.3 of the TRIPS Agreement.

Footnote 58 in the May 11, 2015 version of the TPP corresponds to footnote 5 in the TRIPS, but with the following addition not found in the TRIPS Agreement:

> "In determinations regarding inventive step (or nonobviousness), each Party shall consider whether the claimed invention would have been obvious to a person skilled or having ordinary skill in the art having regard to the prior art."

Paragraph QQ.E.1.3 in the May 11, 2015 draft of the text combines all of the text from paragraphs 27.2 of the TRIPS Agreement and the first sentence of Article 27.3 of the TRIPS Agreement. The reference in Article 27.3 of the TRIPS Agreement regarding an "effective *sui generis* system" is an issue addressed in QQ.E.1.4 of the TPP Text, and also addressed in the requirement in Section A of the IP Chapter (Article QQ.A.8) for TPP members to "ratify or accede" to UPOV 91.

Paragraph QQ.E.1.4 in the May 11, 2015 draft of the text reveals disagreement on the nature of obligations to patent inventions "derived from plants," but apparent agreement to ensure that a sui generis systems "at a minimum, adopts or maintains the standards regarding scope and conditions of protection, scope of rights, exceptions and duration of protection as set forth in UPOV '91."

In the 2013 and 2014 versions, the United States proposed text designed to discourage or ban legislation or policies that mirrored Section 3(d) of the India patent law. The U.S. specifically proposed in Article QQ.E.1(b) that "a Party may not deny a patent solely on the basis that the product did not result in enhanced efficacy of the known product." In the May 11, 2015 draft, this language has disappeared, but in its place is a proposal, opposed only by Chile, that requires patents be granted for at least one of the following: "new uses," "new methods of using" or "new processes of using," for a "known product." Note that while the May 11, 2015 language on new uses, methods of uses or process for known products was based upon earlier proposals, including those found in the 2013 and 2014 leaked texts, the May 11, 2015 version was only opposed by Chile, a significant change in the positions of countries since last year, when only the US, Australia and Japan supported the provision.

Thus, the TPP does require some and perhaps considerable evergreening of the patent protection for known products.

> 2. [US/NZ/SG/AU/JP/CA/PE/MX/BN/VN propose; CL oppose: Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit such processes to those that do not claim the use of the product as such.]

Note that Mexico's earlier efforts to specially allow a party to exclude additional categories of inventions from has been dropped in the 2014 text. What Mexico failed to obtain was the explicit right to exclude patents for:

> the diagrams, plans, rules and methods for carrying out mental processes, playing games or doing business, and mathematical methods as such; software as such, methods to present information as such; and aesthetic creations and artistic or literary works.]

KEI Commentary on Articles QQ.E.8-10.

Articles QQ.E.8-10 also have important rules regarding the granting of patents. QQ.E.8-9 address issue relating to the sufficiency of disclosure. Here the United States and others are seeking to place some boundaries on the required disclosure of know-how or relevance related to patents.

Article QQ.E.10 is a controversial and heavily-bracketed attempt to to require that patents are considered useful when an invention has a “specific, substantial, credible utility.”

Additional Comments on Patents and Evergreening

In the May 11, 2015 draft, Articles QQ.E.1.2 and QQ.E.10 expand obligations to grant patents when inventions involve known products.

The proposed specific obligations in the TPP IP Chapter are more detailed and specific than the WTO TRIPS Agreement in terms of requirements to grant patents on new uses or processes involving known products. The TPP will also be subject to private sector Investor State Dispute Resolution (ISDS), exposing TPP members to large fines if patents are not granted.

One positive aspects of the May 11, 2015 draft is the elimination of language found in earlier versions of the draft text that say:

> "a Party may not deny a patent solely on the basis that the product did not result in an enhanced efficacy of the known product."

Language in all leaked drafts of the TPP text would explicitly require some form of patent grants when known products are involved. The May 11, 2015 draft Article QQ.E.1.2 proposes that patents be available for:

> “at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product.”

There are also provisions in another Article QQ.E.10 which may be interpreted to expand the obligations to grant patents more liberally when the invention involves known products. In the May 11, 2015 draft, this reads as follows:

> Article QQ.E.10: [US/AU/MX/SG propose; [76] CL/MY/VN/PE/BN/NZ/CA oppose: Each Party shall provide that a claimed invention is [US/AU/SG propose: useful] [MX propose: industrially applicable] if it has a specific [MX propose: and], substantial, [MX oppose: and credible] utility.]

If included in the final agreement, Article QQ.E.10, will, among other things, require a finding that an invention is useful if it provides a specific and substantial utility, even when the invention does not involve an enhanced efficacy of the product, including, for example, a combinations of known drugs, or new forms that have different delivery mechanisms. This, taken together with Article QQ.E.2, presents risks to any national effort to reduce the number of evergreening patents on medicines.

Article QQ.E.10 will apply to any patent, including those unrelated to pharmaceutical drugs.

The provisions in QQ.E.10 were opposed by seven TPP members in the March 11, 2015 draft, and could be rejected in the final draft.

Additional comments on TPP and Section 3(d) of the India Patent Act	**India Patent Act**
There has been considerable interest in the degree to which the TPP Articles on patents can be seen as an attack on Section 3(d) of the India Patent Act, which defines “what are not inventions.” The language from the India patent law can be seen both as an exception to patentable subject matter, and a standard for inventive step, and India could defend it either way in a TRIPS dispute. The 3(d) ban on patents for a “new use for a known substance” is in conflict with at least some of the optional obligations to grant patents when known products are involved, set out in Article QQ.E.1.2 of the May 11, 2015 version of TPP negotiating text, and creates obligations that encourage rather than discourage evergreening of patents on drugs and other products. The standards for patents on discovery of new forms, properties or processes that are established in Section 3(d) of the India Act also present a risk of conflict with the March 11, 2015 version of TPP Article QQ.E.10, which uses a different standard for utility in evaluating the inventive step. The proposed TPP standard, opposed in May 11, 2015 by seven countries, is a “specific, substantial [and credible] utility.” To the extent that India would defend its law as a national standard for usefulness or industrial applicability, TPP would be inconsistent. However, India may be able to defend Section portions of Section 3(d) on new forms or process on different grounds.	CHAPTER II - INVENTIONS NOT PATENTABLE **Section 3 - What are not inventions** The following are not. inventions within the meaning of this Act,— . . . (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;