English Translation[1] of Comparison Chart Patent Examination Guidelines 200930

Patent Examination Guideline	Draft Amendment for Patent Examination Guideline (First Batch for Comment)
3.5 On supplementary experimental data Whether or not the description is sufficiently disclosed is judged based on the content recorded in the initial description and claims. Any experimental data submitted after the date of filing an application shall be examined by the examiner. The technical effects demonstrated by the complementary experimental data shall be available to the technicians in the corresponding technical fields from the disclosure in patent applications. According to the examination principles in Section 3.5.1 of this chapter, examples of examination involving drug patent applications are given.	**3.5 On supplementary experimental data** **3.5.1 Examination principles** Whether or not the description is sufficiently disclosed is judged based on the content recorded in the initial description and claims. Any experimental data submitted after the date of filing an application shall be examined by the examiner. The technical effects demonstrated by the complementary experimental data shall be available to the technicians in the corresponding technical fields from the disclosure in patent applications. **3.5.2 Supplementary experimental data for drug patent applications**

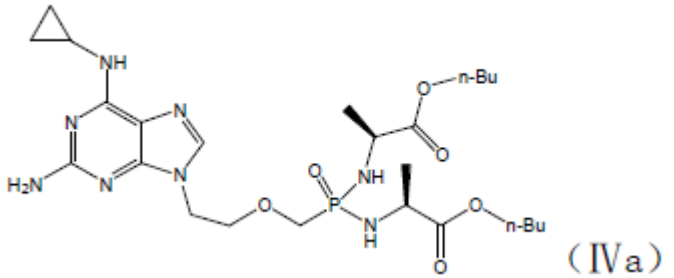
[1]THE USPTO IS PROVIDING THIS TRANSLATION SOLELY AS A CONVENIENCE TO THE ENGLISH-READING PUBLIC. WE HAVE ATTEMPTED TO PROVIDE AN ACCURATE ENGLISH TRANSLATION OF THE CHINESE DOCUMENT, BUT DUE TO THE NUANCES IN TRANSLATING FROM CHINESE TO ENGLISH, SLIGHT DIFFERENCES MAY EXIST. WE WILL MAKE EVERY EFFORT TO CORRECT ERRORS BROUGHT TO OUR ATTENTION.

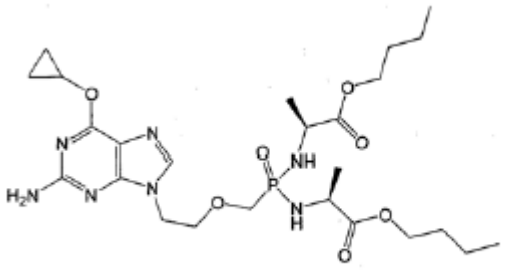
	According to the examination principles in Section 3.5.1 of this chapter, examples of examination involving drug patent applications are given. **[Example 1]** Compound A is claimed; the patent description records the preparation embodiments and blood pressure lowering effect of compound A and the experimental method for the measurement of blood pressure lowering activity, but does not record the experimental results data. In order to prove that the patent description is sufficiently disclosed, the corresponding applicant supplementarily submits the blood pressure lowering effect data of compound A and meanwhile provides the existing technical evidence that compounds with similar structures have blood pressure lowering effect. For technicians in the corresponding technical field, according to the original application documents and the existing technical evidence, the blood pressure lowering effect of compound A has been disclosed and an technical effect to be proved by the supplementary experimental data can be obtained from the disclosures of the patent application documents. **[Example 2]** Compounds of General formula I are claimed; the patent description records the general formula I and its preparation method, and the preparation embodiments of multiple specific compounds such as A and B, and also records the antitumor effect of general formula I, the experimental method for the determination of antitumor activity , and experimental results data; the experimental results data are recorded as the IC50 value of the compounds of embodiments on tumor cells, which is in the range of 10-100nM. In order to prove that the claims have inventive step, the applicant has supplementarily submitted the comparative experimental data, which have shown that the IC50 value of compound A is 15nM, while that of the compound of reference document 1 is 87nM. For technicians in the corresponding

	technical field, according to the records of the original application documents, compound A and its antitumor effect have been disclosed and the technical effect to be proved by supplementary experimental data can be obtained from the disclosures of the patent application documents. It should be noted that at this time, an examiner also needs to further analyze whether the technical solution to be claimed meets the requirements of inventive step in combination with the supplementary experimental data.
Chapter 10, Part II **4.2.3 Other Definition for Claim of Composition** **…** If there is only one property or use of the composition disclosed in the description, the composition ~~shall~~ be drafted as the function-defining or use-defining type, such as (2) or (3) mentioned above. In certain fields, such as the field of alloys, the intrinsic property and/or use of the invented alloy usually shall be specified. Most pharmaceutical claims shall be drafted as the use defining type.	**Chapter 10, Part II** **4.2.3 Other Definitions of claim of composition** … If there is only one property or use of the composition disclosed in the description, the composition usually needs to be drafted as the function-defining or use-defining type, such as (2) or (3) mentioned above. In certain fields, such as the field of alloys, the intrinsic property and/or use of the invented alloy usually shall be specified. Most pharmaceutical claims shall be drafted as the use defining type.
Chapter 10, Part II **5.Novelty of Chemical Invention** **5.1 Novelty of Compound** (1) For a compound claimed in an application, if ~~it has been referred to~~ in a reference document, it is ~~deduced~~ that the compound does not possess novelty, unless the applicant can provide evidence to verify that the compound is not available before the date of filing. ~~The word "refer to" mentioned above means to define clearly or explain the compound by the chemical name, the molecular formula (or structural formula), the physical/chemical parameter(s) or the manufacturing process (including the raw materials to be used).~~ ~~For example, if the name and the molecular formula (or structure formula) of a compound disclosed in a reference document~~	**Chapter 10, Part II** **5. Novelty of chemical invention** **5.1 Novelty of a compound** (1) When a patent application claims a compound, if the chemical name, molecular formula (or structural formula) and other structural information of the compound are recorded in a reference document, and technicians in the corresponding technical field believe that the compound to be claimed has been disclosed, the compound has no novelty unless the applicant can provide evidence to prove that the compound cannot be obtained before the patent application date. If the structural information recorded in a reference document is not sufficient to determine the structural similarities and differences between the compound to be claimed and a compound disclosed in the reference document, but in combination with other information in

~~are difficult to be identified or unclear, but the document discloses the same physical/chemical parameter(s)or any other parameters used to identify the compound as those of the claimed compound of an application, it is deduced that the claimed compound does not possess novelty, unless the applicant can provide evidence to verify that the compound is not available before the date of filing.~~ ~~If the name, molecular formula (or structure formula) and physical/chemical parameter(s)of a compound disclosed in a reference document are unclear, but the document discloses the same method of preparation as that of the claimed compound of an application, it is deduced that the claimed compound does not possess novelty.~~	the reference document, including physical and chemical parameters, preparation method and effect experimental data, etc., after comprehensive consideration, technicians in the corresponding technical field have reason to presume that the two are substantially the same, then the compound to be claimed has no novelty unless the applicant can provide evidence to prove that their structures are indeed different.
Chapter 10, Part II **6.Inventive Step of Chemical Invention** **6.1 Inventive Step of Compound** ~~(1) When a compound is novel, not similar in structure to a known compound, and has a certain use or effect, the examiner may deem it to involve an inventive step without requiring that it shall have an unexpected use or effect.~~ ~~(2) For a compound that is similar in structure to a known compound, it must have unexpected use or effect. The said unexpected use or effect may be a use different from that of the known compound, the substantive progress or improvement of a known effect of a known compound, or a use or effect which is not clear in the common general knowledge or cannot be deduced from the common general knowledge.~~ ~~(3) Whether two compounds are similar in structure has relation to the technical field of the compounds, the examiner shall apply~~	**Chapter 10, Part II** **6. Creativity of chemical invention** **6.1 Creativity of a compound** (1) To judge the inventive step of a compound invention, it is necessary to determine the structural differences between the compound to be claimed and the compound closest to the existing technology, and to determine the technical problems actually solved by the invention through the use and/or effect obtained on the basis of the structural modification, and on this basis, to judge whether the existing technology as a whole provides technical enlightenment for solving the described technical problems through the structural modification. It should be noted that if technicians in the corresponding technical field can carry out the structural modification to solve the described technical problems and obtain the compound to be claimed just through logical analysis, reasoning or limited tests on the basis of the existing technology, it is believed that the existing technology has technical enlightenment.

~~different criteria to different technical fields. The following are some examples:~~ [Example 1] … ~~The compounds with similar structures must have the identical basic core structure or basic rings.~~ ~~As the structure of~~ (Ⅰb) ~~is not similar to that of~~ (Ⅰa), ~~when determining the inventive step of (Ⅰb), no evidence is necessary to show that (Ⅰb) has an unexpected use or effect compared with (Ⅰa).~~ [Example 2] … Sulfonamide (Ⅱa) is an antibiotics, and sulfonylurea (Ⅱb) an antidiabetic. ~~They are similar in structure but different in pharmaceutical effect.~~ The (Ⅱb) involves an inventive step ~~because it has unexpected use or effect~~. [Example 3] … The ~~structure~~ of amino-sulfonylurea (Ⅲa) ~~is similar~~ to that of methyl-sulfonylurea (Ⅲb). The difference lies in NH 2and CH 3only. ~~Being short of unexpected use or effect~~, (Ⅲb) does not involve an inventive step. ~~(4) It shall be noted that the inventive step of a compound ought not to be denied simply on the grounds of structural similarity. It is necessary to further explain that its use or effect can be expected or is predictable, or that a person skilled in the art is able to produce or use that compound by logical analysis, inference or limited experiment on the basis of the prior art.~~ ~~(5) If the effect of a technical solution is caused by something known and inevitable, the technical solution does not involve an inventive step. For example, an insecticide A-R is in the prior art,~~	(2) The use and/or effect brought by the structural modification of a compound closest to the existing technology by using the invention may be to obtain a different use from that of the known compound, or may be an improvement on the effect in a certain aspect of the known compound. When the inventive step of a compound is judged, if the change in use and/or the improvement of the effect is unexpected, it reflects that the compound to be claimed is non-obvious and its inventive step should be recognized. (3) It should be noted that when the inventive step of a compound is judged, if the effect of the technical solution to be claimed is caused by a known inevitable trend, the technical solution has no inventive step. For example, an insecticide A-R of the existing technology, wherein R is a C1-3 alkyl, and it has pointed out that the insecticidal effect improves as number of C atoms of alkyl increases. If a certain insecticide applied for is A-C4H9 and its insecticidal effect is significantly improved compared with that of the existing technology, the application has no inventive step since the existing technology has pointed out the inevitable trend of improving insecticidal effect. (4) Examples of judgment on inventive step [Example 1] … The core structures of (Ib) and (Ia) are different, but both have the same use. Technicians in the corresponding technical field generally believe that compounds with close structures have the same or similar uses, and close structures generally mean that compounds have the same basic core part or basic ring. The existing technology has no technical enlightenment that the basic ring of (Ia) is modified to obtain (Ib) and the use remains unchanged, so (Ib) has inventive step. [Example 2]

~~wherein, R is C1-3alkyl. It has been pointed out in the prior art that the effectiveness of insecticide is improved with the increase of the number of atom in the alkyl. If the insecticide in an application is A-C4H9, the effectiveness has been obviously improved compared with the prior art. The application does not involve an inventive step because it has been pointed out in the prior art that the improved effectiveness of the insecticide is inevitable.~~	… (IIb) is formed by the insertion of -CONH- into NHR1 structural fragment of (IIa), and the two have completely different uses: (IIa) sulfonamide is an antibiotic, while (IIb) sulfonylurea is an antidiabetic. Technicians in the corresponding technical field have no motivation to modify R1 in an antibiotic to CONHR1 to obtain an antidiabetic, so (IIb) has inventive step. [Example 3] … (Ⅲa) amino-sulfonylurea and (Ⅲb) methyl-sulfonylurea only differ in their structures: NH2 in the former and CH3 in the latter. Both are antidiabetics with equivalent effect. Compared with (Ⅲa), (Ⅲb) provides another antidiabetic in the corresponding technical field. Since NH2 and CH3 are classical univalent isosteres, technicians in the corresponding technical field have motivation to carry out the isosteric substitution in order to obtain the same or equivalent antidiabetic activity, so (Ⅲb) has no inventive step. [Example 4] The existing technology:  (Ⅳa) Application:



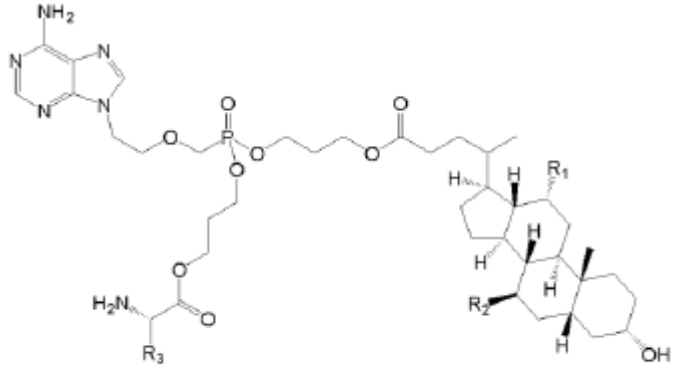
(43)

(IVb)

Difference between compound (IVb) and compound (IVa) is only that -O- substitutes -NH- at site 6- of purine. The -O- and -NH- are well-known classical isosteres in the corresponding technical field, however, the growth inhibition activity of cancer cells of (IVb) is about 40 times higher than that of (IVa), and compared with (IVa), (IVb) has achieved an unexpected technical effect which reflects that (IVb) is non-obvious, so (IVb) has inventive step.

[Example 5]

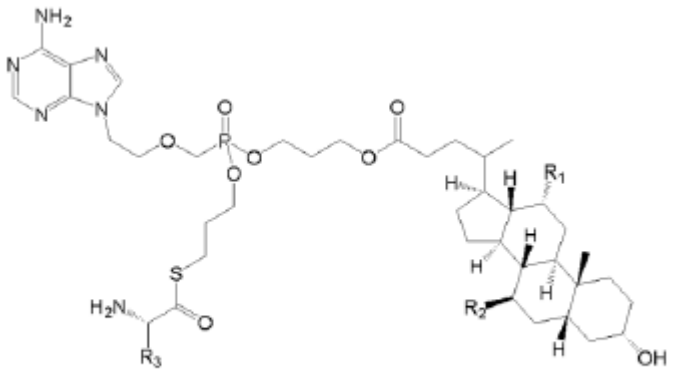
The existing technology:



(Va)

Wherein R1=OH, R2=H and R3=CH2CH(CH3)2.

Application:



（Vb）

Wherein R1 and R2 are selected from H or OH, R3 is selected from C1-6 alkyl, and a specific compound (Vb1) is included wherein R1=OH, R2=H and R3=CHCH3CH2CH3. Besides, the anti-hepatitis B virus activity of (Vb1) is significantly better than (Va).

When compounds of general formula (Vb) are claimed, difference between (Vb) and (Va) is only the difference in a connecting atom between phosphoryl alkyl and amino acid residue: -S- is in (Vb), while -O- is in (Va). Compared with (Va), a compound of the general formula (Vb) provides another anti-hepatitis B virus drug in the corresponding technical field. Since the properties of -S- and -O- are close, in order to obtain other drugs that also have anti-hepatitis B virus activity, technicians in the corresponding technical field have motivation to carry out the substitution and obtain a compound of the described general formula (Ⅴb), so (Ⅴb) has no inventive step.

When a specific compound (Vb1) is claimed, difference between (Vb1) and (Va) is not only the aforementioned linking atom, but also the substituent at site R3. The anti-hepatitis B virus activity of (Vb1) is significantly better than that of (Va). The existing technology has no technical enlightenment for improving the anti-hepatitis B virus activity through the described structural modification, so (Vb1) has inventive step.

Chapter 10, Part II **9.2 Sufficient Disclosure of the Description** **9.2.1 Deposit of Biological Material** (4) The depositary institutions designated by the State Intellectual Property Office refer to the international depository institutions for biological material samples acknowledged by the Budapest Treaty, including the Center for General Microorganism of the Administration Committee of the China Microbiological Culture Collection (CGMCC)based in Beijing ~~and~~ the China Center for Type Culture Collection (CCTCC)based in Wuhan.	**Chapter 10, Part II** **9.2 Sufficient disclosure of patient description** **9.2.1 Deposit of biological materials** (4) The depositary institution designated by China National Intellectual Property Administration refer to the international biological material samples depositary institution acknowledged by the Budapest Treaty, including China General Microbiological Culture Collection Center (CGMCC) of China Committee for Culture Collection of Microorganisms in Beijing in China, China Center for Type Culture Collection (CCTCC) in Wuhan, and Guangdong Microbial Culture Collection Center (GDMCC) in Guangzhou.
Chapter 10, Part II **9.3 Claims of Inventions in the Field of Biotechnology** **9.3.1 Inventions Relating to Genetic Engineering** **9.3.1.7 Monoclonal Antibody** A claim directed to a monoclonal antibody may be defined by specifying hybridoma which produces it. [Example] A monoclonal antibody against antigen A, produced by a hybridoma having CGMCC Deposit No.xxx.	**Chapter 10, Part II** **9.3 Claims for inventions in the biotechnical field** **9.3.1 Inventions involving genetic engineering** **9.3.1.7 Monoclonal antibody** Claims for a monoclonal antibody can be defined by the structural features or by a hybridoma that produces it. [Example] (1) A monoclonal antibody against antigen A, which includes amino acid sequences VHCDR1, VHCDR2 and VHCDR3 as shown in SEQ ID NO: 1-3, and amino acid sequences VLCDR1, VLCDR2 and VLCDR3 as shown in SEQ ID NO: 4-6. (2) A monoclonal antibody against antigen A is produced by a hybridoma with deposit number CGMCC NO:xxx.
Chapter 10, Part II **9.4.2 Inventive Step** **9.4.2.1 Inventions Relating to Genetic Engineering**	**Chapter 10, Part II** **9.4.2 Inventive Step**

(1) Gene Where a protein is known, but its amino acid sequence is not, an invention of a gene encoding the protein does not involve an inventive step if a person skilled in the art can readily determine the amino acid sequence at the time of filing. However, when the gene has a specific base sequence and has technical effects compared with other genes having a different base sequence encoding said protein, which a person skilled in the art cannot expect, the invention of said gene involves an inventive step. ~~If the amino acid sequence of a protein is known, an invention of a gene encoding the protein does not involve an inventive step. However, if the gene has a particular base sequence and has technical effects compared with other genes having a different base sequence encoding said protein, which a person skilled in the art cannot expect, the invention of said gene involves an inventive step.~~ If the claimed structural gene of an invention is the naturally obtainable mutant of a known structural gene and that the claimed gene is derived from the same species as that of the known structural gene and has the same properties and functions as those of the known structural gene, then the invention does not involve an inventive step. (~~2~~) Recombinant vector If both a vector and an inserted gene are known, an invention of a recombinant vector obtained by a combination of the two usually does not involve an inventive step. However, if an invention of a recombinant vector with a specific combination of them can produce unexpected technical effects compared with the prior art, the invention involves an inventive step. (~~3~~) Transformant	In order to judge the inventive step of an invention in the biotechnical field, it is also necessary to judge whether the invention has outstanding substantive features and significant progress. In the judging process, it is necessary to determine the distinguishing features between the invention and the closest existing technology based on the specifically limited contents of different subjects to be claimed, and then to determine the technical problems actually solved by the invention based on the technical effect that the distinguishing features can achieve in the invention, and next, to judge whether the existing technology as a whole provides technical enlightenment; on this basis, whether relative to the existing technology the invention is obvious can be concluded. Inventions and creations in the biotechnical field involve subjects to be claimed at different levels such as biological macromolecules, cells and individual microorganisms. In ways to characterize these subjects to be claimed, besides the common ways such as structures and compositions, there are also special ways such as deposit numbers of biological materials. Judgment on inventive step needs to consider the structural differences between an invention and the existing technology, distance of relative relationship, predictability of technical effect, etc. The following shows some specific situations in the inventive step judgments of different subjects to be claimed in this field. **9.4.2.1 Inventions relating to genetic engineering** (1) Gene If compared to a known protein, a protein encoded by a structural gene has a different amino acid sequence and a different type of property or improved property and the existing technology does not provide technical enlightenment that the sequence difference brings the aforementioned property change, then the gene invention encoding the protein has inventive step.

If both a host and an inserted gene are known, an invention of a transformant obtained by a combination of them generally does not involve an inventive step. However, if an invention of a transformant obtained from a specific combination of them can produce unexpected technical effects compared with the prior art, it involves an inventive step. (~~4~~) Fused cell If parent cells are known, an invention of a fused cell produced by fusing the parent cells does not involve an inventive step. However, if the fused cell has an unexpected technical effects compared with the prior art, the invention of the fused cell involves an inventive step. (~~5~~) Monoclonal antibody If an antigen is known and it is clearly known that the antigen has immunogenicity (for example, said antigen clearly has immunogenicity because a polyclonal antibody of the antigen is known or the antigen is a polypeptide with a large molecular weight), the invention of a monoclonal antibody of the antigen does not involve an inventive step. However, if the invention is further defined by other features, and hence has unexpected technical effects, the invention of that monoclonal antibody involves an inventive step.	If the amino acid sequence of a protein is known, the invention of the gene encoding the protein has no inventive step. If a protein is known but its amino acid sequence is unknown, as long as technicians in the corresponding technical field can easily determine its amino acid sequence when the application is filed, the invention of the gene encoding the protein has no inventive step. However, in the aforementioned two situations, if the gene has a specific base sequence and has an effect not expected by technicians in the corresponding technical field compared with other genes with different base sequence encoding the protein, the invention of the gene has inventive step. If the structural gene to be claimed of an invention is a naturally available mutant structural gene of a known structural gene, and the structural gene to be claimed and the known structural gene are derived from the same species, and they also have the same properties and functions, then the invention has no inventive step. (2) Polypeptides or proteins If the polypeptide or protein to be claimed of an invention is different from any known polypeptide or protein in amino acid sequence and has different types of property or improved properties, and the existing technology does not provide technical enlightenment for the aforementioned property changes caused by the sequence difference, then the invention of the polypeptide or protein has inventive step. (3) Recombinant vector If aiming at structural modification of a known vector and/or an inserted gene, an invention has achieved an improvement of the property of a recombinant vector, and the existing technology does not provide technical enlightenment for using the aforementioned

	structural modification to improve property, then the invention of the recombinant vector has inventive step. If both of a vector and an inserted gene are known, the invention of a recombinant vector obtained by their combination usually has no inventive step. However, if an invention of a recombinant vector formed by their specific combination has an unexpected technical effect compared with the existing technology, the invention of the recombinant vector has inventive step. (4) Transformants If aiming at structural modification of a known host and/or an inserted gene, an invention has achieved an improvement of the property of a transformant, and the existing technology does not provide technical enlightenment for using the aforementioned structural modification to improve property, then the invention of the transformant has inventive step. If both of a host and an inserted gene are known, the invention of a transformant obtained by their combination usually has no inventive step. However, if an invention of a transformant formed by their specific combination has an unexpected technical effect compared with the existing technology, the invention of the transformant has inventive step. (5) Fusion cells If parental cells are known, the invention of fusion cells obtained by the fusion of these parental cells usually has no inventive step; however, if the fusion cell has an unexpected technical effect compared with the existing technology, the invention of the fusion cell has inventive step. (6) Monoclonal antibodies If an antigen is known, a monoclonal antibody of the antigen characterized by the structural features is significantly different from

	any known monoclonal antibody in the key sequence determining functions and uses, and the existing technology does not provide technical enlightenment for obtaining the monoclonal antibody with the aforementioned sequence and the monoclonal antibody can produce beneficial technical effect, then the invention of the monoclonal antibody has inventive step. If an antigen is known and it is very clear that the antigen has immunogenicity (for example, if a polyclonal antibody of the antigen is known or the fact that the antigen is a macromolecular polypeptide can conclude that the antigen has obvious immunogenicity), then the invention of a monoclonal antibody defined only against the antigen has no inventive step. However, if the invention is further defined by a hybridoma secreting the monoclonal antibody against the antigen and thus produces an unexpected effect, the invention of the monoclonal antibody has inventive step.