U.S. Patent Application: Drafting the Claims

美国专利申请：如何撰写权利要求

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Agenda

- Basic Requirements
- Claims and Drafting Claims
- Effective filing date and Prior Art
- Drafting Claims in view of 35 USC 101/102/103
- Conclusion

Requirement for obtaining allowable claims --获得可授权权利要求的条件

- **Claims:**
  - Define the metes and bound (界限/范围) of the invention
- **35 USC 101** - Determine whether your invention contains patentable subject matter
  - Composition, process, machine, manufacture, or improvement thereof
    - No abstract ideas, natural laws or natural phenomenon
- **35 USC 102 and 103** - Novelty and Non-obviousness
  - Consider whether there is prior art of your invention that would render your invention anticipated or obvious
- **35 USC 112** - Drafting the Specification and Claims
  - Must be enabling
    - Should demonstrate applicant had possession of the invention

Claims/权利要求

- Types /类型
  - Composition/组成或配方
  - Process or Method / 工艺或方法
  - Machine / 机器
  - Manufacture / 制造
  - Improvement thereof / 上述的改进

- Claims are the **MOST important** part/最重要的部分
  - The remaining portion of the application (e.g. written description, figures, examples) is meant to provide support for the claims. /专利的其他部分（如说明书，附图，实施例）是为权利要求提供支持的。
  - In order to find infringement, every limitation of the claim must be found in the allegedly infringing process, apparatus or composition of matter./权利要求中的全部“限制”都可在某一工艺/设备/组成中找到，侵权方可成立

Claims Format （格式） (1 of 3)

- Preamble （序言）(MPEP 2111.02)
  - General description of the elements/steps to be claimed, given at the beginning of a claim.
    - Ex: A method of treating cancer...

- Transition words （过渡词） (MPEP 2111.03)
  - Open ended （开放式的）: recited elements are not all the possible elements; i.e., unnamed elements can still be part of the claimed combination
    - “Comprising”, “including”, “having” (包含)
  - Closed ended（封闭式的）: recited elements excludes other elements
    - “Consisting of”, (= “仅包含”)
    - Ex: A method of treating cancer “consisting” the steps of….

- Body （主体）(MPEP 2164.08(c))
  - Sets forth what the invention covers and should be a description of what excludes others from practicing your invention. 阐述了本发明所涵盖的内容，应该是一个排除他人使用该发明的一个描述。

Claim Format （格式） (2 of 3)

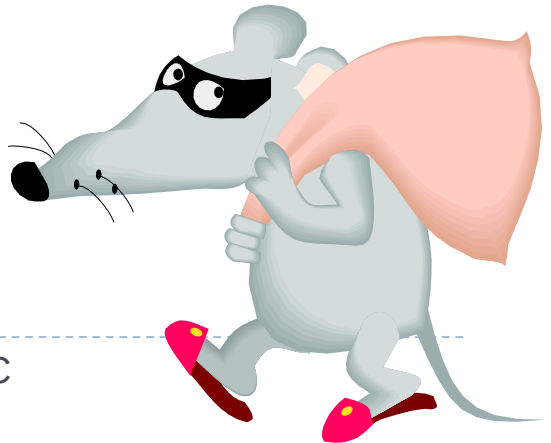
- Types of Claims / 权利要求的类别
  - Independent （独立权利要求）
    - Broadest claim （范围最宽的一项权利要求）
      - Ex: “1. A method for treating diabetes...”
  - Dependent （从属权利要求）
    - Recites embodiments and depends from a previously listed claim.
    - 引述具体细节，且从属于一项前述权利要求
      - Ex: “2. The method of claim 1, wherein …”
      - Ex: “3. The method of claim 1, wherein …”
    - Multiple Dependent （多重从属权利要求）
      - Claim which depends from more than one previously listed claim. / 从属于多项前述权利要求
        - Ex: “4. The method of claim 2 or 3, wherein …”

Claim Format （格式） (3 of 3)

- Formatting
  - Number the claims consecutively
  - The first reference to a claim limitation should be recited with an indefinite article “a”, “an”
  - Subsequent references to a claim limitation should be recited with a definite article “the”
    - However, if the limitation is inherent to an element then using “the” is permissible in the first reference to the limitation.
      - Ex: “the right arm of the patient”; “the circumference of the sphere”

Scope of Claims (权利要求范围)

- Claims should range from broad to narrow
  - Start with a broad independent claim /开始是宽的独立权利要求
  - Then limit through dependent claims/ 然后，通过从属权利要求，进一步限制
- When drafting claims, consider how a third party may infringe your patent. / 考虑第三方如何专利侵权
  - To find infringement every limitation of the claims must be met. / 权利要求的所有限制都需满足才可以定为侵权
  - Try to draft claims that will prevent a third party from “designing around” your patent. 撰写的权利要求应**避免**第三方“**绕过**”该专利



Claim Drafting in view of 35 USC 101

35 USC 101 (适格性要求）

- Whoever invents or discovers any new and useful **process, machine, manufacture, or composition of matter, or any new and useful improvement thereof**, may obtain a patent therefor, subject to the conditions and requirements of this title.

Ineligible subject matter (不可专利的客体）:

- abstract ideas
  - Mathematical equation / 数学公式
- laws of nature 自然规律
- natural phenomena (including products of nature) /自然现象
  - DNA

Effective Filing Date (有效申请日期), and Prior Art （现有技术）

Effective Filing Date (有效申请日期)

It is the earlier of:

- (1) the actual filing date of the patent or the application containing a claim to the invention / 实际提交日; or
- (2) the filing date of the earliest priority application (i.e., the earliest filed provisional, nonprovisional, international, or foreign application) to which a patent or patent application is entitled to a right of priority for the claimed invention / 最早的优先权日.

- Evaluated on a claim-by-claim basis. / 每项权利要求的有效申请日或不相同。

Prior Art (现有技术)

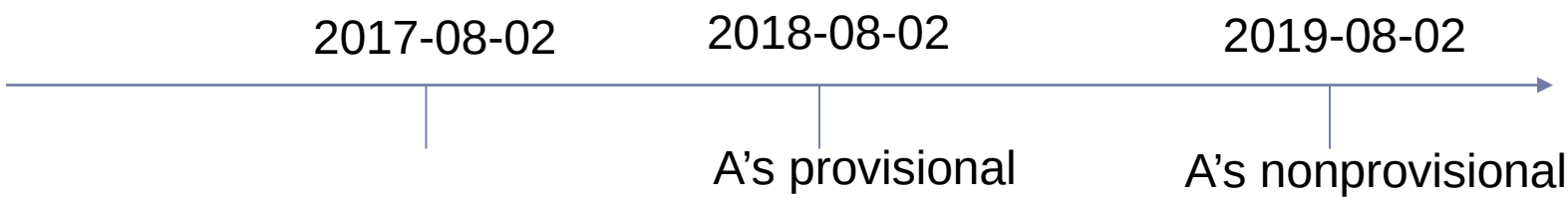
35 USC 102 precludes a patent if the claimed invention was**,**
before the effective filing date,

- Patented,
- described in a printed publication,
- in public use,
- on sale,
- or otherwise available to the public;

One Year Grace Period in US / 美国有一年的宽限期

- Disclosure made by the inventor or others who obtained directly/indirectly from the inventor

Example: Inventor =A;



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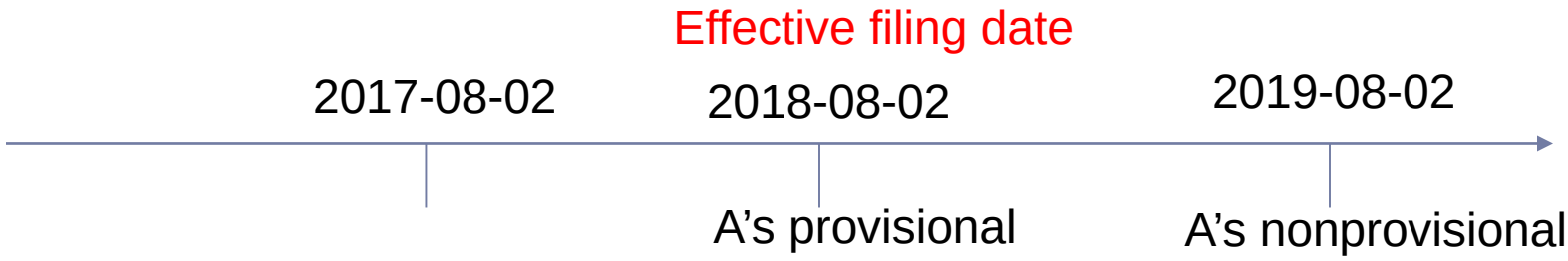

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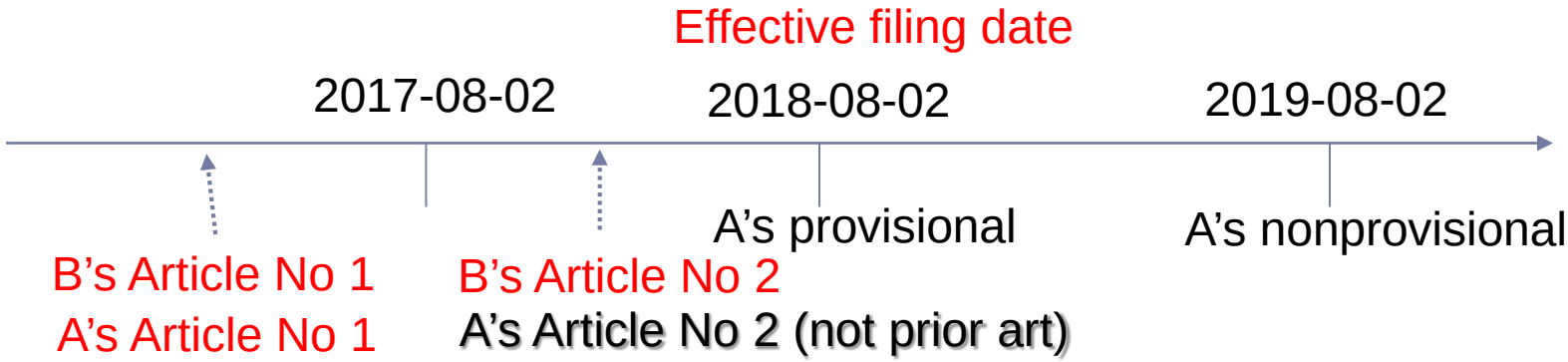


Prior Art Search / 现有技术检索/查新

- Prior art search
  - Patent literature 专利文献
  - Non-patent literature 非专利文献

- Draft claim in view of known prior art / 基于知道的现有技术撰写权利要求
  - Increase certainty about patent prosecution in the future / 增加未来专利申请过程中的确定性

Draft claims in view of prior art
基于现有技术撰写权利要求

35 U.S.C. 102

35 U.S.C. 102

A person shall be entitled to a patent unless the invention:

(1) was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2) described in a patent … or in an application for patent published or deemed published … in which the patent or application… names another inventor and was effectively filed before the effective filing date of the claimed inventio.

One Year Grace Period in US / 美国一年的宽限期

- Only applicable to disclosure made directly/indirectly from the inventor / 仅适用于由发明人直接或间接做出的披露

Lacking Novelty/Anticipation /新颖性

- Lacking novelty/anticipation – when a single prior art disclosure teaches at least one complete embodiment within the scope of a claim
  - Element/limitation of the claim may be expressly or inherently described in one **single** prior art disclosure / 单个现有技术明确地或者固有地批露了权利要求中的所有的元素和限制

Claim Elements/Limitations vs Claim Breath

- **Claim elements/limitation 元素/限制**
  - The individual components required by the claim that together make up an embodiment of the claimed invention
- **Claim Breadth/ 范围**
  - The full range of embodiments of the invention that the claim encompasses or covers / 权利要求所囊括或包含的全部发明实施范围
- **For a prior art to anticipate**
  - Must teach all elements/limitations of at least one embodiment of the claim
  - Only need to teach one embodiment within the breadth of the claim / 只需教导权利要求中的一项实施范围

35 USC 103 Nonobviousness (非显而易见性)

35 U.S.C. § 103(a) (AIA)

A patent for a claimed invention may not be obtained, … if the differences between the claimed invention and the prior art are such that the claimed invention **as a whole would have been obvious before the effective filing date of** the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

- A single reference does not need to teach all aspects of the claimed invention.

KSR International Co. v. Teleflex Inc.

In 2007, the Supreme Court's *KSR* decision reaffirmed that the familiar *Graham v. Deere* analysis, requiring evaluation of

1. the scope and content of the prior art;
2. the difference between the prior art and the claimed invention;
3. the level of ordinary skill in the art; and
4. secondary considerations

TSM Test / TSM测试

- A claim is obvious when there is a **teaching, suggestion**, or **motivation** to combine prior art teachings. / 当存在结合多个现有技术的教导、暗示或动机时，即，显而易见
- The teaching, suggestion, or motivation may be found in the prior art, in the nature of the problem, or in the knowledge of a person having ordinary skill in the art. /这些教导、建议或动机可在现有技术、问题本身、或者本领域技术人员的知识中发现。
- Supreme Court: the TSM test is not the only rationale to support a conclusion of obviousness./ 美国最高法院：TSM测试不是“显而易见”结论的唯一理由。

Typical Scenarios for combining multiple references /多篇文献结合的常见情形

A. Combining Prior Art Elements / 多个现有技术元素的组合
B. Substituting One Known Element for Another /用已知现有元素取代
C. Obvious To Try / 明显可试

A. Combining Prior Art Elements: *Sundance, Inc. v. DeMonte Fabricating Ltd.*

The claimed segmented （分开的） and mechanized （机械的） cover （保护罩） for trucks, swimming pools, or other structures was obvious over the prior art applied.

- One reference taught that a reason for making a segmented cover was ease of repair / 一篇文献教导了制作分开保护罩的理由是易于修复
- A second reference taught the advantages of a mechanized cover for ease of opening. / 第二篇文献教导了机械保护罩的优点是易于打开

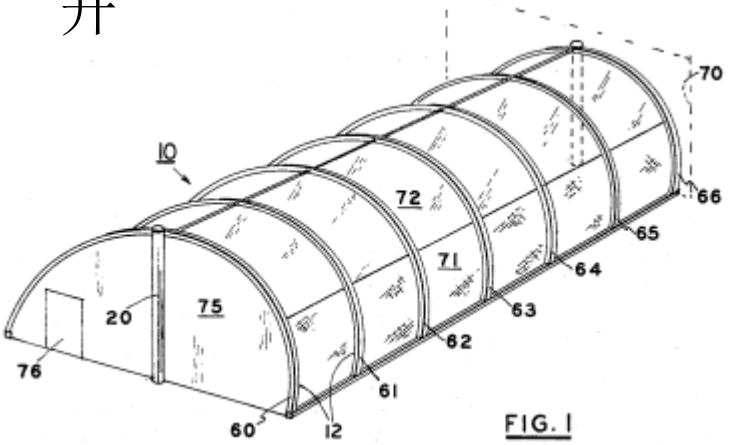
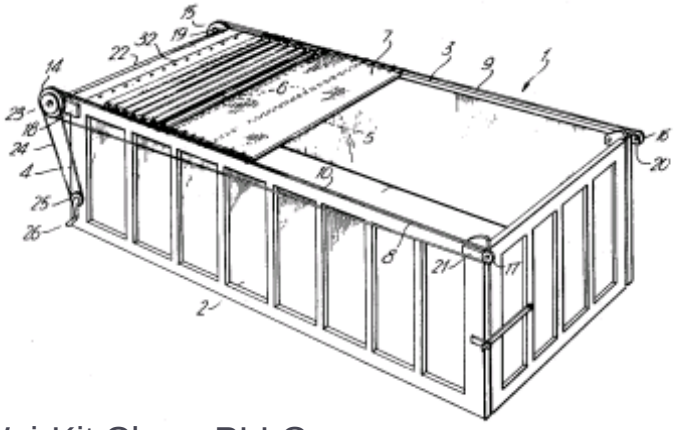


FIG. 1



A. Combining Prior Art Elements:
Sundance, Inc. v. DeMonte Fabricating Ltd.

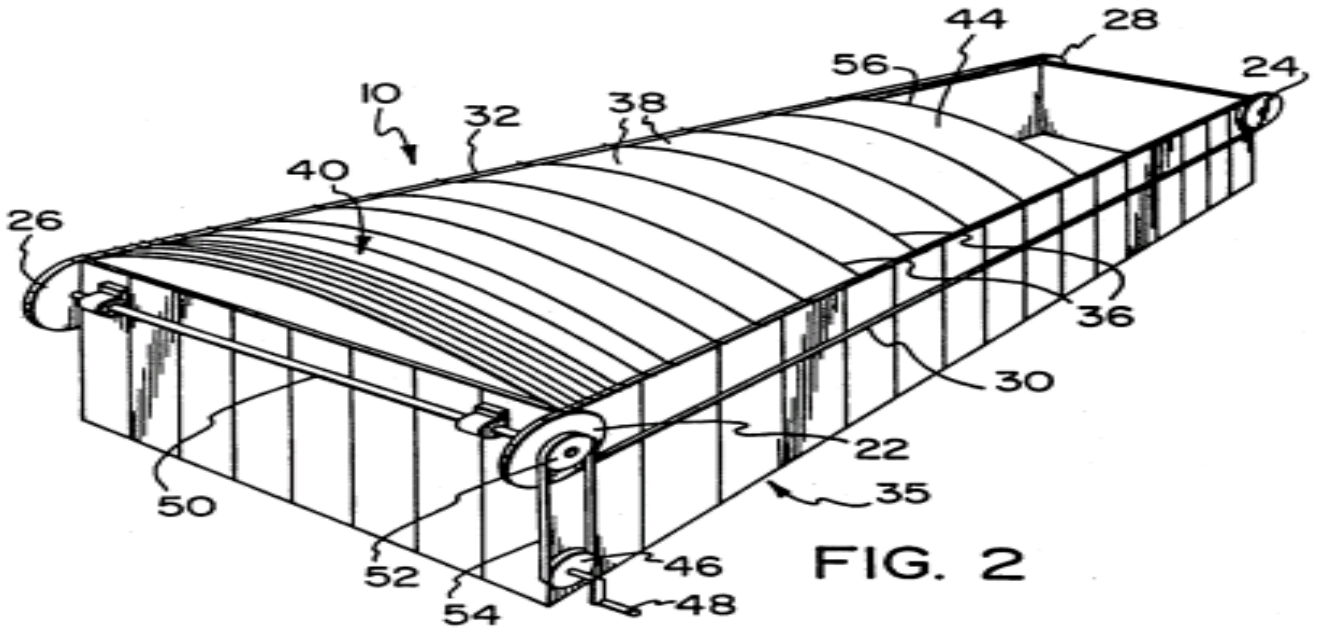


FIG. 2

A. Combining Prior Art Elements: *Sundance, Inc. v. DeMonte Fabricating Ltd.*

Why was the claimed segmented and mechanized cover obvious?

- 两者结合后，这两项功能的实现方式一样。
- 本领域普通技术人员可通过将“可取代分块”加到第“机械化保护罩上”。

Teaching point/要点:

- A claim is obvious if it is a combination of known prior art elements that would reasonably have been expected to maintain their respective properties or functions after they have been combined. /如果已知现有技术元素在结合后人们可以预见其性能或功能，那么，这个原理要求是“显而易见”的

A. Combining Prior Art Elements: *In re Omeprazole Patent Litigation*

The claimed pharmaceutical formulation including **two layers of coatings** over the active ingredient omeprazole (奥美拉唑) (marketed as Prilosec®) was **not obvious**, even though

- the coating materials and methods for applying them were known / 包衣材料和方法已知
- a formulation of omeprazole and a **single-layer coating** was known / 单层包衣的配方已知
- using a coating and a subcoating was known generally, although not specifically for omeprazole / 通常而言，使用包衣和亚包衣已知，尽管不是针对这个药物

A. Combining Prior Art Elements: In re Omeprazole Patent Litigation

Why was the claimed formulation **nonobvious**?

- Discovered that the single-coating prior art product was subject to degradation, and that the degradation could be reduced by adding a subcoating. / 发现单层包衣的现有产品会降解，该降解可通过添加一个亚包衣而降低。

- Absent prior recognition of the problem, there would have been no reason to add a subcoating. Even though the modification would have been technically feasible, it would have amounted to extra effort and expense for no expected return without the patentee's discovery of the problem. / 倘若没有发现问题，人们没有理由增加一个亚包衣。即使这种改进技术上简单，没有发现该问题，人们会花费大量时间和费用且得不到任何回报。

A. Combining Prior Art Elements: In re Omeprazole Patent Litigation

Teaching point/要点:

- Even where a general method that could have been applied to make the claimed product was known and within the level of skill of the ordinary artisan, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown.
- 即使一个通用的方法
  - 可适用于所要求的产品是已知的，
  - 在普通技术人员的水平之内，
- 如果建议使用该方法的技术问题是未知的，

- **那么，权利要求或不是显而易见的**

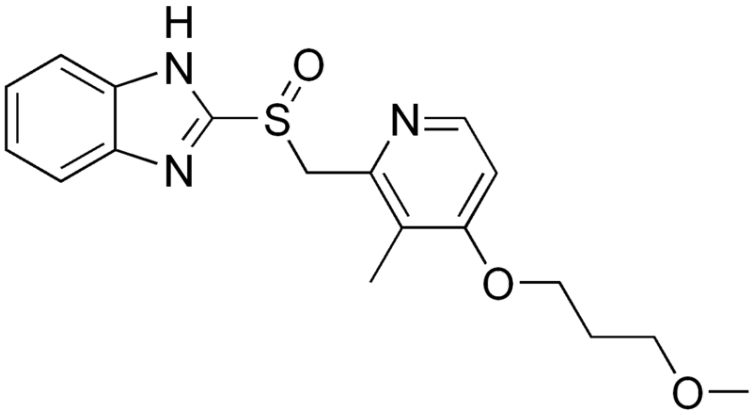
B. Substituting One Known Element for Another: *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*

The claimed compound rabeprazole (雷贝拉唑), a proton pump inhibitor for treating stomach ulcers and related disorders, was **nonobvious** over the prior art references applied, even though

- The prior art compound lansoprazole shared a common core structure with rabeprazole and was useful for the same indications.
- Lansoprazole differed from rabeprazole only in that it had a trifluoroethoxy (三氟乙氧基) substituent in place of a methoxypropoxy (甲氧基丙氧基) substituent, and therefore was suitable as a lead compound (先导化合物/先导物).

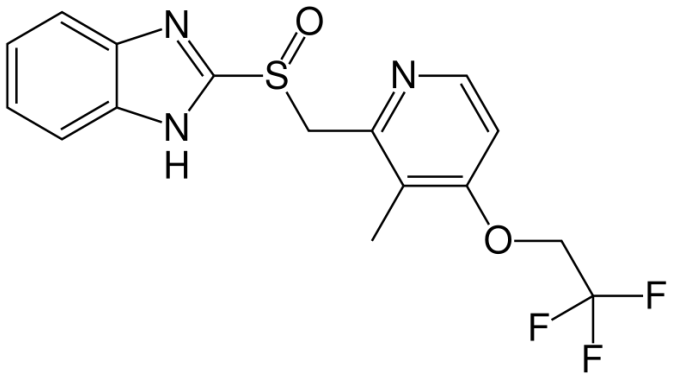
B. Substituting One Known Element for Another: Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.

- Claims
- RABEPRAZOLE
（雷贝拉唑）



Prior Art

LANSOPRAZOLE
(兰索拉唑)



B. Substituting One Known Element for Another: *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*

Why was the claimed compound rabeprazole **nonobvious**?

- There was no sufficient reason advanced for modifying lansoprazole. / 没有充分理由进一步改动兰索拉唑

- The prior art created the expectation that rabeprazole would be less useful than lansoprazole because the proposed modification would have been expected to reduce the lipophilicity of the compound. Lipophilicity was known to be an advantageous property for such compounds. / 在先技术创立了这样一个预期：**雷贝拉唑**可能不能和**兰索拉唑**一样有效， 因为该改动降低其亲酯性。而亲酯性被认为是此类化合物的一优异性能。

C. Obvious To Try: *In re Kubin*

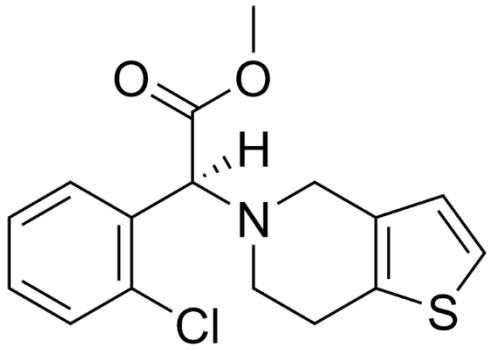
The claimed isolated nucleic acid molecule was obvious.

- The polypeptide encoded by the claimed nucleic acid was known by partial structure and binding properties. /权利要求所列核糖酸所解码的多肽，其部分结够和结合性能已知
- The prior art taught that a skilled artisan would have been able to make the claimed nucleic acid using standard biochemical techniques. / 在先技术教导了本领域普通技术人员可通过标准生化技术方法来制作所要求的核糖酸
- There would have been a reasonable expectation of success. / 这里会有一个合理的成功的希望。

C. Obvious To Try:
Sanofi-Synthelabo v. Apotex, Inc.

The claimed anti-thrombotic compound clopidogrel (氯吡格雷), which is the **dextrorotatory isomer (右旋异构体)** of methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate, was **nonobvious** over the prior art applied, even though:

CLOPIDOGREL
氯吡格雷



- Racemate (外消旋), or mixture of dextrorotatory and levorotatory (D- and L-) isomers of the compound, was known in the prior art
- The mixture was known to have anti-thrombotic properties

C. Obvious To Try: *Sanofi-Synthelabo v. Apotex, Inc.*

Why was the claimed dextrorotatory isomer clopidogrel **nonobvious**?

- The two isomers had not previously been separated. / 这两种消旋体之前未被分离过
- Although the mixture was known to have anti-thrombotic properties, the extent to which each of the individual isomers contributed to the observed properties of the racemate was not known and was not predictable. / 尽管混合物均有抗血栓性能，任何其中单个异构体对混合物的性能未知，且不可预测
- The D-isomer had unusually advantageous properties, and researchers had thought that separating the isomers would be unproductive. That is, persons of ordinary skill in the art, prior to the separation of the isomers, would have had no reason to expect that the D-isomer would have such strong therapeutic advantages as compared with the L-isomer. In other words, the result had been unexpected. / 右旋异构体具有超级优良的性能，研究人员曾认为分离两者是不可生产的。即，在分离之前，普通技术人员没有理由期望**右旋异构体**具有如此强大的治疗效果。换言之，其结果是不可预期的。

C. Obvious To Try:
Sanofi-Synthelabo v. Apotex, Inc.

Teaching point/要点:

- A claimed isolated stereoisomer would not have been obvious where the claimed stereoisomer exhibits unexpectedly results over the prior art racemic mixture, and the resulting properties of the enantiomers separated from the racemic mixture were unpredictable.
- 当分离的异构体，与现有技术的混合物相比，展现出不可预期的效果时，该分离的异构体不是显而易见的

Takeaway

- Claims are the most important part of a patent.
- A claim consists of a preamble, a transition word and a body.
- A patentable claim must be directed to one of the four eligible categories, i.e., process, machine, manufacture, or composition (35 USC 101) and should not be abstract ideas, natural laws or natural phenomenon.
- Effective filing date is the earlier of a) actual filing date, or b) the priority date as claimed.
- Prior art can be any thing that is publicly available before the effective filing date subject to certain exceptions.
- With known prior art, claims should be drafted in a way that they are distinguished from prior art, i.e., novel under 35 USC 102 and not obvious under 35 USC 103.

THANK YOU FOR YOUR TIME

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