中国公司生物技术发明的专利保护策略

Patent Strategy for Biotech Inventions of Chinese Companies

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不同场合对生物技术发明的描述须保持一致

Description of bio-inventions at different situations shall be consistent

- 生物技术发明往往需要多次公开，如果不同场合的描述彼此矛盾，可能会产生麻烦
- 专利说明书；审查意见答复;专利无效答辩
- 专利诉讼中的陈述
- 向药监局提交的新药报批资料；药品说明书
- 学术论文
- 同一公司名下的其他专利中的数据和陈述

- It's quite common to disclose bio-inventions several times. If the descriptions at different situations are inconsistent, problems may arise.
- Patent specification; reply to office action; observations in patent invalidation
- Observations in litigation
- New drug application submitted to SFDA; drug specification
- Academic articles
- Data and statements in other patents of the same company

新药报批资料可能会成为对本方不利的证据

New drug application material might become unfavorable evidence

- 伊莱利利诉江苏豪森制药专利侵权案(最高人民法院(2002)民三终字第8号)
- 伊莱利利的专利涉及“新产品”盐酸吉西他滨的制备方法。豪森制药向法院提供的制备方法与专利方法明显不同。法院通过向药监局调档发现豪森制药向法院提供的制备方法与备案资料不一致，判其败诉。

- ELi Lily V. Jiangsu Haosen Pharmaceutical (Supreme Court (2002) MSZ No.8)
- The patent of Eli Lilly relates to the preparation process of a “new product” gemcitabine hydrochloride. The preparation process as provided by Haosen to the court was different with the patent. The court found upon ordering a file from SFDA that the process provided to the court was inconsistent with the new drug application materials and thereby made an unfavorable judgment.

论文与专利不一致可能导致专利无效

Inconsistent description in articles may lead to invalidation of patent

- 施贵宝诉罗纳普朗克公司专利侵权案，**326 F.3d 1226 (F.C.2003)**
- 发明人在论文中宣称，只有在“具有特定保护基和独特反应条件下”，专利方法才能成功实现。
- 法国专利申请和相应美国申请中未包含所述的两个限制条件。
- 美国法院以“不正当行为”为由判决专利不可执行。

- Bristol-Myers Squibb Co. V. Rhone-Poulenc Rorer Inc., 326 F.3d 1226 (Fed. Cir. 2003)
- The inventors stated that the method "could be successfully achieved only with specific protecting groups and under unique reaction conditions”.
- French and corresponding US patent applications do not contain the two limitations described in article.
- The US court found patent unenforceable for inequitable conduct.

公司名下的其他专利可能被用于反对本专利

Other patents of the company may be used to object to this patent

- 湖北午时药业诉澳诺(中国)制药专利侵权案(最高人民法院(2009)民提字第20号)
- 澳诺制药的专利涉及防治钙质缺损的药物，其中包含谷氨酰胺或谷氨酸。午时药业的口服液中包含盐酸赖氨酸。澳诺制药援引药监局文件主张盐酸赖氨酸可代替谷氨酸，二者构成等同。
- 法院发现，在澳诺制药的另一篇专利中，通过试验数据证明以盐酸赖氨酸代替谷氨酸取得了意想不到的技术效果，因而判定这两个特征不等同。

- Hubei Wushi Pharmaceutical V. O Connaught (China) Pharmaceutical (Supreme Court (2009) MTZ No.20)
- The patent of O Connaught relates to a medicament for preventing calcium deficiency, comprising glutamine or glutamate. The oral liquid of Wushi comprises lysine hydrochloride. O Connaught alleged by citing an official document of SFDA that lysine hydrochloride may be used to replace glutamate, which are equivalent.
- The court found in another patent of O Connaught that it was demonstrated by test data that replacement of glutamate by lysine hydrochloride produces unexpected effects and thereby ruled that the two features were not equivalent.

诉讼中的在先陈述可能会成为败诉原因

Prior statement in the litigation may lead to failure

- 昆明制药集团诉昆明龙津药业专利侵权案(云南省高级人民法院（2003）云高民三终字第48号)
- 昆明制药专利提到针剂含有5-30%重量的灯盏花素盐。龙津药业的针剂含有43%重量的灯盏花素盐。昆明制药主张该含量构成等同。
- 法院发现昆明制药在此前的技术鉴定程序中曾指出“灯盏花素盐的含量与本案有关，应进行检验”，因而根据禁止反悔原则判定不构成等同侵权。

- Kunming Pharmaceutical Group V. Kunming Longjin Pharmaceutical (Yunnan High Court (2003) YGMSZ No.48)
- Kunming Pharmaceutical's patent recites the injection comprises 5-30 wt% of Breviscapine salt. The injection of Longjin comprises 43 wt% of Breviscapine salt, which is alleged by Kunming Pharmaceutical to be equivalent.
- The court found Kunming Pharmaceutical alleged in earlier technical appraisal that “content of Breviscapine salt is relevant and shall be tested”, and thereby found no equivalent infringement based on doctrine of estoppels.

禁止反悔原则的适用日趋严厉

Doctrine of estoppels is becoming stricter

- 2009年司法解释第6条：“专利申请人、专利权人在专利授权或者无效宣告程序中，通过对权利要求、说明书的修改或者意见陈述而放弃的技术方案，权利人在侵犯专利权纠纷案件中又将其纳入专利权保护范围的，人民法院不予支持。”（没有提到修改目的）
- 最高人民法院在2010年3月23日作出的(2009)民提字第20号判决书中进一步明确，无论该修改或者意见陈述是否与专利的新颖性或者创造性有关，均产生禁止反悔的后果。

- Article 6 of 2009 Judicial Interpretations: “Technical solutions abandoned by the applicant or patentee in prosecution or invalidation procedure **by amendments or observations** shall not be included in patent protection scope in infringment litigation.” (purpose of amendments is not mentioned)
- Supreme Court further clarified in Judgment (2009) MTZ No.20 of March 23, 2010 that the amendments or observations will be subject to estoppels regardless whether they are related to patentability or not.

对策

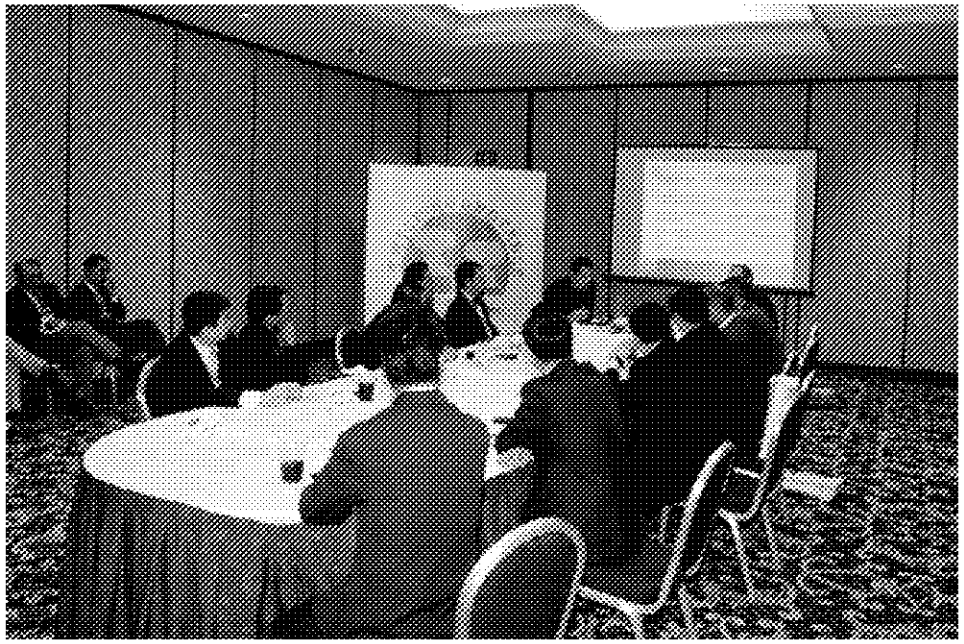
Recommendations

- 专利申请、诉讼、新药申请和论文由不同部门分头负责往往是问题产生的原因；由IP部门集中协调管理或寻求外部顾问的意见会有所帮助。
- 在撰写申请和发表意见时应以事实为依据；在禁止反悔原则适用日趋严厉的情况下，“见风使舵”后患多。
- 在专利申请和诉讼中要明确本方的底线和目标，防止陈述彼此矛盾，自乱阵脚。
- 在专利数量和进入国家较多时，需协调好各平行专利的关系。

- Problem may arise from parallel management of patent prosecution, litigation, new drug application and academic publishing by different organs. Centralized management by IP department or seeking opinions from outside counsel may be of help.
- Patent drafting and observations shall be based on facts.
- The bottom line and target in patent prosecution and litigation should be clear so as to avoid inconsistent presentations.
- Where the number of patents and countries entered are large, patents in parallel should be managed in harmonization.

当你的专利被盯上以后……

When your patent becomes the target of others ……



如果桌上放着的就是你的专利，你有信心能经受住考验么？

If the documents on the table are just your patents, do you have enough confidence to survive from the challenges?

专利布局中的"国际化"问题

"Internationalization" issue in patent strategy

- 生物发明研究周期长、投入大、保密难，对专利保护依赖性高
- 核心专利几乎都要进入多个国家（中国各领域平均2国/PCT）
- 从全球来看，生物发明的申请和诉讼难度大、争议多、规定复杂
- 各国关于生物发明的法律规定差别大，国际申请撰写难度高
- 中国公司受国内法影响较大，"国际化"意识相对薄弱，专利价值偏低

- Bio-inventions require long-term research, high investment and are difficult to keep secret, and thereby rely heavily on patent protection.
- Key patents usually enter multiple states (2 states/PCT application from CN)
- Prosecution and litigation of bio-inventions are difficult worldwide
- Laws on bio-inventions in various states are quite different; drafting of PCT international application is challenging
- Most Chinese companies are greatly influenced by domestic legislation, "Internationalization" degree is poor; value of patents is relatively low

尽职调查中的常见问题

Frequent problems in due diligence

- 公开早，授权快，范围窄，错误多
- 没有外国专利（考量因子 CN 30%, US 30%, JP/EP各20%）
- 权利归属有瑕疵
- 发明人列举随意
- 隐匿最佳模式
- 漏交IDS(信息披露声明)
- 协调管理不够，专利申请、诉讼、新药申请、论文之间互相打架

- Early publication, quick grant, narrow scope, many errors
- No foreign patents (evaluation factor CN 30%, US 30%, JP/EP 20%)
- Flaws in ownership
- Problematic inventorship
- Absence of best mode
- Missing IDS (Information Disclosure Statement)
- Poor management, leading to inconsistent presentations in patent prosecution, litigation, new drug application and academic publishing

撰写国际申请时需了解主要目的国的法律

Knowledge of laws of major target states is crucial in drafting PCT

- 中国对于试验数据、修改和支持性要求很高（美欧要求低）
- 中国公司受国内法影响大，偏于保守
- 发明人列举错误在美国可能导致整个专利无效(10作者/3发明人)
- 隐匿最佳模式在美国可能导致整个专利无效
- 漏交IDS文献可能导致“不正当行为”
- 美加日韩俄巴墨等国的广义宽限期可在论文不慎发表时予以补救
- 原始权项过多可能导致高额费用(中日按公布权项数收费)

- Requirements to test data, amendments and support in China are very high (US/EP not so high)
- Chinese companies influenced by domestic legislation and thus conservative
- Erroneous inventorship may lead to unenforceability of whole patent (10 authors / 3 inventors)
- Absence of best mode may lead to unenforceability of whole patent
- Missing IDS reference may lead to “inequitable conduct”
- US/CA/JP/KR/RU/BR/MX provides broad novelty grace period in rescue of early publication of articles
- Too many claims leading to huge cost (fees based on publication in CN/JP)

中国对于生物技术发明的试验数据要求很高

High requirements to test data for bio-inventions in China

- 试验数据与充分公开、创造性、实用性及支持性密切相关
- 试验数据充分与否直接决定案件能否授权及保护范围大小
- 尽管对数据的要求很高，但是补救机会却非常有限
- 申请日后提交的证明充分公开或支持性的试验数据一般不予接受
- 就创造性补交的试验数据应当是针对现有技术的对比试验证据，并且必须针对原申请中明确记载且给出了相应试验数据的技术效果。

- Test data closely related to sufficient disclosure, inventiveness, industrial applicability and support
- Test data decide whether a patent can be granted and scope of protection
- Though requirements to data are high, opportunity of rescue is very limited
- Data furnished after filing date in favor of sufficient disclosure or support usually unacceptable
- Data supporting inventiveness shall be results of comparative tests over prior art, and shall be directed to those technical effects which are clearly disclosed in specification and for which relevant data have been provided.

活性数据是否有足够说服力？

Activity data convincing?

- 案例1:
- 现有技术需加入100 ppm以下的酸，优选10-30 ppm。本发明加入的酸为100 ppm以上，优选200-300 ppm。实施例中测试了60 ppm和240 ppm,其中240 ppm效果很好，60 ppm不能完成反应。
- 请问：200-300 ppm这个范围能被允许么？假如让你撰写说明书，你会怎么做？

- Case 1:
- Prior art method adds an acid of below 100 ppm, preferably 10-30 ppm. The present invention adds an acid of at least 100 ppm, preferably 200-300 ppm. In the examples, 60 ppm and 240 ppm are tested, wherein result for 240 ppm is excellent, and reaction is not completed at 60 ppm.
- Question: Is the scope of 200-300 ppm allowable? What will you do if you are drafting the specification?

是否存在负面数据？
Are there negative data?

- 案例2:
- 本专利涉及制备核苷的方法。说明书中公开了104个实施例，但是其中11个实施例表明落在权利要求范围内的部分技术方案不能实现发明目的，即存在所谓的“负面实施例”。最终专利因支持问题被无效。

- Case 2:
- The patent relates to a method for preparing nucleoside. 104 examples are disclosed in the specification, wherein 11 examples demonstrate that some technical solutions within claims are impracticable; in other words, there exist so called “negative examples”. The patent was finally invalidated for lack of support.

北京市高级人民法院（2008）高行终字第451号行政判决书
Beijing High Court (2008) GXZ No. 451

试验数据准确么？

Test data correct and accurate?

- 案例3:
- 将萃取液蒸干，获得3.2g粗品……称取6克粗品溶于氯仿，充分震荡，形成均一溶液。

- Case 3:
- 3.2 g of crude product was obtained after evaporating the extract…... 6 g of the crude product was weighed and dissolved into chloroform, forming a uniform solution.

问题产生于从另一篇相关论文复制试验方法时的错误

Problem arose from a mistake in copying test methods from another article

医药用途有活性数据证明么？

Are there activity data supporting the medical use?

- 案例4:
- 本发明涉及将两种药物联合给药治疗呕吐的方法。说明书中宣称两种药物的联合给药提供了协同治疗作用，但没有提供活性数据加以证明。本案最终以公开不充分为由被驳回。

- Case 4:
- The invention relates to a method for treating nausea by combined administration of two drugs. It is alleged in the description that combined administration of the two drugs provides a synergistic effect, for which no activity data are disclosed. The application was finally rejected for insufficient disclosure.

第4679号复审请求审查决定
Reexamination Decision No. 4679

实施例中有证明蛋白功能的活性数据么？

Are there activity data demonstrating protein's function in examples?

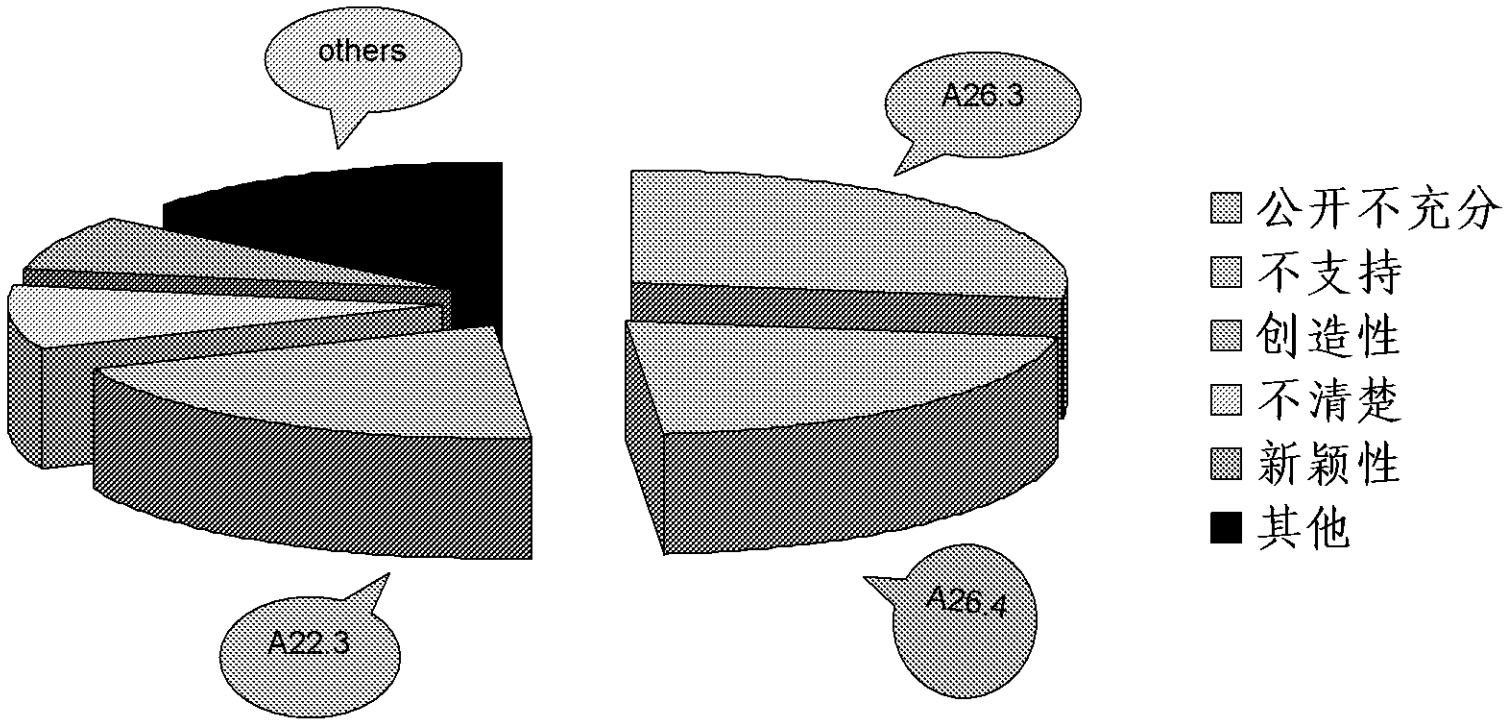
- 案例5:
- 本发明涉及与人G蛋白偶联的孤儿受体(GPCR)及编码基因。说明书中提供了序列比对结果，检测了基因的组织表达特异性,但没有提供活性数据证明GPCR的功能。本案最终以公开不充分为由被驳回。
- Case 5:
- The invention relates to orphan human G protein-coupled receptors (GPCR) and encoding gene. The description provides sequence alignment results, and tissue specificity of gene expression is tested. However, no activity data is disclosed to demonstrate the function of GPCR. The application was finally rejected for insufficient disclosure.

第12619号复审请求审查决定

Reexamination Decision No. 12619

数据不足是生物发明的重要驳回理由

Insufficient data are important ground for rejection of Bio-inventions



对策
Recommendations

- 高度重视试验数据的准备
- 提交申请前再度确认：试验设计是否合理？有无对照？试验结果是否有说服力？有无统计显著性？步骤能否重复？结论能否成立？
- 待试验数据初步完备后再提交申请
- 如试验一时无法完成，可先在美国或欧洲提交申请

- Pay much attention to preparation of test data
- Confirm before filing: design of tests reasonable? Is there a control? Test results convincing? Results statistically significant? Steps repeatable? Conclusion tenable?
- File patents only after test data are preliminarily complete
- If tests cannot be completed for the time being, file patents in US or EP first.

防范术语"不清楚"

Be careful of "unclear" terms

- 化学领域“不清楚”的反对意见出现频繁(平均约63%，398/631)
- 多数“不清楚”问题可以通过修改或者意见陈述克服；有些则是不可克服的致命缺陷
- 常见的“不清楚”问题:
  术语缺少定义（低级醇、基本上无水、衍生物）
  缩写形式含义不确定（LP、THF、PHA、DP_4）
  上位概念和下位概念并列(活性钙、氯化钙)
  百分数缺少单位

- "Unclear" rejection appears frequently in chemistry (63% in ave., 398/631)
- Most unclear issues may be overcome by amendment or explanation; while some are irreparable fatal defects
- Common "unclear" expressions:
  undefined terms (lower alcohol, substantially unhydrous, derivative)
  indefinitive abbreviations (LP, THF, PHA, DP_4)
  upper concept and lower concept in parallel (active calcium, $CaCl_2$)
  lack of unit for percentages

本以为很清楚的词可能含义不唯一

A “clear” term may have several meanings

- 案例6:
- 权利要求中提到关键物质“低级醇”。审查员认为该术语不清楚。可惜的是，说明书中没有给出“低级醇”的定义，而在不同的词典中，其定义各不相同，可以指C1-C4的醇，也可以指C1-C6的醇。最后只能根据实施例将其限定为“乙醇”。这使得专利的保护范围过于狭窄，基本上失去了市场价值。

- Case 6:
- A key substance “lower alcohol” is recited in claims, which is rejected by the examiner for being unclear. Unfortunately, no definition of the term is given in specification, while the definitions provided in dictionaries are different, which may refer to C1-C4 alcohol, or C1-C6 alcohol. The applicant has to limit the term to “ethanol” based on examples. This renders the patent protection scope too narrow and market value of the patent is almost lost.

使用自造词时务必给出定义

Always give definition to self-created terms

- 案例7:
- 权利要求涉及具有血管舒缓素生成抑制活性的兔皮，其具有大于或等于0.5iu/g的SART活性。说明书中没有给出“SART活性”的定义，也没有给出测定方法，专利权人也承认“iu/g”是一个自定义的单位。该权利要求最终被判定无效。

- Case 7:
- Claim recites a rabbit skin having kallikrein production inhibiting activity, which has a **SART activity of 0.5iu/g** or above. No definition or test method of “SART activity” is provided in the specification. The patentee also recognized that “iu/g” is a self-created unit. The claim was finally invalidated for being unclear.

北京市高级人民法院(2009)高行终字第527号行政判决书
Beijing High Court (2009) GXZ No. 527

谨慎使用简写

Use of abbreviations should be cautious

- 案例8:
- 权利要求1涉及一种包衣食品，包含0.7-1.5％重量的DP_4。此处的简写“DP_4”是本发明区别于现有技术的核心特征，但是在说明书中没有任何定义或者解释，也没有给出全称。在复审过程中，审查员举证证明该术语含义不唯一，导致专利申请最终被驳回。

- Case 8:
- Claim recites a coated food, comprising 0.7-1.5 wt% of DP_4. The abbreviation “DP_4” is the distinguishing feature over prior art, while no definition, explanation or full name of the term is given in the specification. During reexamination, the examiner demonstrated by evidences that the term has several different meanings, which led to final rejection of the application.

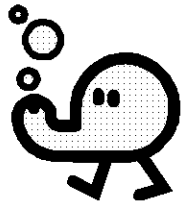
第14104号复审请求审查决定
Reexamination Decision No. 14104

关键参数需有测定方法

Test method of key parameters shall be provided

- 案例9:
- 权利要求1：一种威士忌，其特征在于，其酒香指数为12－20。
- 用于表征威士忌的关键参数“酒香指数”是申请人自定义的一个参数，申请日前本领域技术人员不知道其具体含义，无法测定。因此该权利要求不清楚，而且无法挽救。

- Case 9:
- Claim 1: A whisky, having a fragrance index of 12-20.
- The key parameter “fragrance index ” used to define the whisky is a self-created term by the applicant. A skilled artisan does not know its meaning before filing date and thus cannot measure it. Therefore the claim is unclear, which is irreparable.



上下位概念并列后果可能很严重

Terrible result may occur by listing upper and lower concepts in parallel

- 案例10:
- 原权项1包含可溶性钙剂。说明书定义可溶性钙剂包括葡萄糖酸钙和活性钙等。2个实施例中分别使用了葡萄糖酸钙和活性钙。后因支持问题权项1中的可溶性钙剂被修改为活性钙。被控侵权产品刚好含有葡萄糖酸钙。专利权人主张活性钙包含葡萄糖酸钙。法院认为上述描述方式表明二者为并列的可溶性钙剂，葡萄糖酸钙已经通过修改放弃，因而不得再主张权利。

- Case 10:
- Original claim 1 recites soluble calcium. Specification defines that soluble calcium includes calcium gluconate and active calcium etc. The two examples are directed to calcium gluconate and active calcium respectively. The soluble calcium in claim 1 was amended to active calcium later for support issue. The alleged infringing product just contains calcium gluconate. Patentee alleged active calcium includes calcium gluconate. Court ruled that the above description indicates the two substances are alternatives in parallel; calcium gluconate has been abandoned by amendment, and thus cannot be claimed again.

最高人民法院(2009)民提字第20号
Supreme Court (2009) MTZ No.20

对策
Recommendations

- 对权利要求中的术语逐一进行评估
- 重要术语、含义不明确的术语和自造词均应有定义或解释
- 简写应给出全称或外文原文
- 数值应给出单位
- 提交前再次确认用语准确严谨，符合科学规范

- Evaluate each term used in claims
- Important terms, indefinitive terms and self-created terms should be defined or explained
- Full name or foreign language of an abbreviation should be provided
- Unit of numerals should be given
- Confirm before filing that terms are accurate and standard, complying with scientific standards

撰写专利说明书并非易事

Patent drafting is challenging

- “很少有比专利说明书更加难以起草、更加充满陷阱的法律文件了”(Circuit Judge Newman)
- 撰写专利说明书需要掌握相当全面的专利知识（专利局+法院+外国法+商业考量）
- 要求发明人写出高水平的专利说明书几乎是不可能完成的任务。发明人的主要任务就是帮助你的律师理解发明并准备好技术交底书。

- “There are few, if any, legal documents more difficult to craft, more fraught with pitfalls than patent applications” (Circuit Judge Newman)
- Patent drafting requires comprehensive patent knowledge (patent office+court+foreign patent laws+commercial considerations)
- It is almost an impossible mission for inventors to draft a perfect specification. Major tasks of inventors are to help your attorney understand the invention and to prepare an invention disclosure.

发明人如何准备技术交底书？

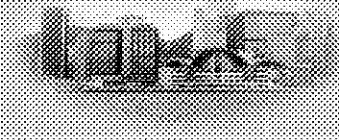
How to prepare invention disclosure as an inventor?

- 采用自己最擅长的方式将所做研究描述清楚即可；可以写成论文或试验报告，也可以口述。
- 通常包括已有技术的情况、研究目的、研究思路、试验方法和材料、试验结果、结论和启示、最具商业价值的部分等。
- 试验部分应当规范、准确、完整，符合科技文献的一般要求
- 申请一旦提交修改机会将相当有限(几乎不允许出错)

- Describe the research clearly in a manner you are familiar with; research article, experiment report and oral presentation are all acceptable.
- Usually include prior arts, purpose of research, materials and methods, results, conclusions and discussion, commercially valuable parts etc..
- Tests should be accurate and complete, complying with scientific standards
- Opportunity of amendment will be limited once filed (errors almost intolerant)

感谢聆听！

Thank you!



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