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ASIA
LIFE SCIENCES
亚洲生命科学

Introduction to US Intellectual Property
对美国知识产权的介绍

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Presenter

演讲者



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Agenda 目录

- Intellectual Property (IP) 知识产权
- Patents Basics 专利概述
- Scope and Duration of Patent Protection 专利保护的范围和时长
- Trade Secret 商业秘密
- Patent Licensing 专利许可



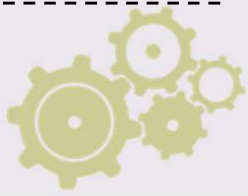


Intellectual Property 知识产权

- Patents 专利
 - Right to exclude
 - 排他权
- Trade Secrets 商业秘密
 - Information that is secret and derives economic value from being secret
 - 保密的信息, 并且因保密状态而具备经济价值
 - Examples: recipes, techniques/processes, compilations of information
 - 举例: 配方, 技术或流程, 信息汇编
- Trademarks 商标
 - Words, symbols, colors, sounds or smells that serve as identification of the source of goods or services
 - 用于识别商品或服务来源的文字、标识、颜色、声音或气味
- Copyrights 版权
 - Creative works in tangible form
 - 有形的创意产品

What is a Patent? 什么是专利？

- A patent is the *right to **exclude*** others from making, using, selling, or offering to sell or importing the patented invention during the term of the patent
- 专利是一项**排除**他人在专利有效期内制造、使用、销售或提供销售或进口专利发明的权利。
 - Does not give right to make, practice, or sell the invention
 - 不给予制造、使用或销售该发明的权利。
- Limited term
- 有期限
- Territorial: A U.S. patent provides protection only in the United States
- 地域：美国的专利只在美国领土境内提供保护

Exemplary Categories of Patent Protection in Biopharma 生物制药业专利保护的典型种类

| Composition of Matter 物质组成 | Formulation 配方 | Method of Making 制作方法 | Method of Use 使用方法 | Delivery Device 药物递送装置 |
|--|--|---|--|--|
| <ul style="list-style-type: none"> Specific reference product (gene and protein sequences; compound) 具体的参考药品 (基因和蛋白质序列; 化合物) Most readily discoverable and referenced patent 最容易被发现和可参考的专利 | <ul style="list-style-type: none"> The mixture of the protein/compound is presented within 蛋白质或化合物所承载的混合物 Various formulations, e.g., liquid, powder for reconstitution, etc. 不同的配方, 例如液体、用于重组的粉末等 | <ul style="list-style-type: none"> The process used to create the product 用于制作药品的流程 Specific to each individual manufacturer's process 每个生产商不同的工艺 | <ul style="list-style-type: none"> How the product is administered 药品如何服用 Can be related to strength, indication, dosage schedule, administration type, etc. 可与药效强度、适应症、剂量安排、药品类型等有关 | <ul style="list-style-type: none"> The delivery device for the product 用于传送药物至人体体内的装置 Delivery devices are created to best administer the product and then patented as proprietary 药物递送装置是为了最好地管理药品而生, 并被登记为专有技术 |
|  |  |  |  |  |

Why File Patents 为什么要申请专利

- **Defensive 防御**
 - Discourage litigation, encourage cross-licensing, provide design freedom.
 - 阻止诉讼 · 鼓励交叉许可 · 提供设计自由。
- **Protection of R&D Investment 保护研发投入**
 - Prevent free-riding, enable valuation of technology.
 - 防止搭便车 · 实现技术评估。
- **Licensing 许可**
 - Generate royalty stream, enable technology transfer.
 - 产生特许使用费用 · 允许技术转让。
- **Competitive Advantage / Support Product Revenue 竞争优势/支持产品收入**
 - Exclusionary remedy, preclude or conform competition, barriers to entry, protect revenue from patented products (e.g., pharma).
 - 排他性, 排除或顺应竞争 · 行业准入壁垒 · 保护专利产品的收入 (例如制药业)。
- **Strategic Partnerships, Consortia 战略合作伙伴 · 联合关系**
 - Enhance status in partnerships, use to influence/guide standards.
 - 提高合作关系中的地位, 用于影响或引领标准。
- **Encourage Employee Inventors 鼓励员工发明**
 - Enhance employee reputation due to public identification as inventors
 - 提高员工被大众认定为发明者的声誉
 - Patent Award programs benefit employees financially
 - 专利奖计划使员工获得经济利益
- **Enhance Company Reputation as Innovator 提高公司作为创新者的声誉**
 - Helps company establish reputation as innovator
 - 有助于公司树立创新者的名望
 - Helps attract employees who are innovators
 - 有助于吸引有创造力的员工

Life Cycle Management (LCM) 生命周期管理

Goal of Patenting Biologics:

Extend Patent Exclusivity as long as possible

为生物制品申请专利的目标：
尽可能延长专利独占性的时间

Early: "first generation" patents: Composition of matter

Later: "life cycle management" patents: dosing regimen, combination therapy, method of making, etc.

早期：“第一代”专利：物质组成

后期：“生命周期管理”专利：给药方案、组合疗法、制作方法等。



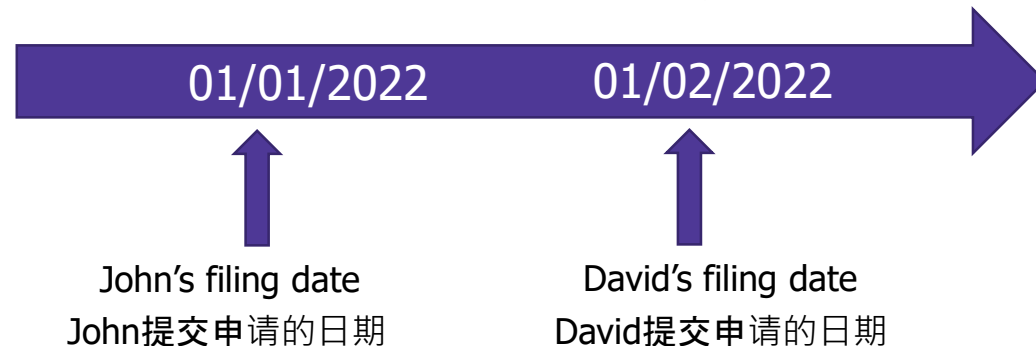
What to Patent 什么可以申请专利

- File patent applications for any technology that is CORE, DIFFERENTIATING or LICENSABLE
- 为任何**核心的、差异化的或可授权的**技术提出专利申请
 - Differentiating Technology - makes products better.
 - 差异化技术--使产品更好。
 - Core or Future Technology - key company strength, focus of business and/or R&D.
 - 核心或未来技术--公司的关键力量，业务和/或研发的重点。
 - Licensable - of interest to other parties, probably non-core technology.
 - 可授权的技术--其他各方感兴趣的，可能是非核心技术。
- File patent application only if infringement is DETECTABLE - otherwise, better to keep invention as Trade Secret (e.g., Coca Cola formula)
- 只有在**侵权行为可被发现**的情况下才提出专利申请--否则，最好将发明作为商业秘密保留（例如，可口可乐的配方）。
 - YES: User Interfaces and readily identifiable product features.
 - 是：用户界面和容易识别的产品特征。

First to file-America Invents Act (AIA)

优先申请- 《美国发明法案》

- United States patent applications filed after March 16, 2013 are subject to a rule commonly referred to as "first inventor to file."
- 2013年3月16日之后提交的美国专利申请，须遵守通常称为“第一发明者提交”的规则。
- Before March 16, 2013 , the United States operated on what was commonly referred to as a "first to invent" rule.
- 在2013年3月16日之前，美国实行的是通常称为“首次发明”规则。
- Therefore, timely filing an invention is important to protect Iovance IP assets.
- 因此，及时提交专利申请对保护Iovance的知识产权资产非常重要。



- John's application would be prior art over David's application-one day ahead.
- John的专利申请早于David一天被认可为现有技术。

Duration – United States

专利保护期--美国

- If filed on or before June 8, 1995如果在1995年6月8日及之前申请，
 - 17 years from issue date 自许可发行之日起17年
- Currently 现在
 - 20 years from filing dated 自申请之日起20年
 - Patent Term Extension 专利期延长
 - one drug, one patent 一个药物，一个专利
 - Up to 5 years based on the formula: 最长为5年，根据公式计算：
 - (1/2 time in clinic testing phase) + the time of the approval phase
 - (临床测试阶段用时的1/2)+批准阶段用时
 - European Supplemental Protection Certificate 欧盟补充保护证书 (欧洲专利权延长制度)

Anatomy of a Patent 专利的剖析

Issue date
发行日期

- Abstract 摘要
 - A short summary of the invention.
 - 关于发明的简要概括
- Written description 书面描述
 - How does it work?
How is it made or used?
 - 该产品如何起效？它如何制作而成或者如何使用？
- Drawings 配图
 - What does it look like?
 - 该产品长什么样？
- Claims 权利要求
 - The claim(s) define(s) the legal boundaries of the invention, similar to a deed to a property.
 - 权利要求界定了发明的法律边界，类似于房产契约。

Invention title
发明名称

Assignee name
受让人姓名

Filing date
申请日期

| | |
|--|---|
| (12) United States Patent Wardell et al. | (10) Patent No.: US 10,894,063 B2 (45) Date of Patent: *Jan. 19, 2021 |
| (54) PROCESSES FOR PRODUCTION OF TUMOR INFILTRATING LYMPHOCYTES AND USES OF SAME IN IMMUNOTHERAPY | 2501/2321 (2013.01); C12N 2501/24 (2013.01); C12N 2502/11 (2013.01) |
| (71) Applicant: Invance Biotherapeutics, Inc. , San Carlos, CA (US) | (58) Field of Classification Search None See application file for complete search history. |
| (72) Inventors: Seth Wardell , Tampa, FL (US); James Bender , Rancho Santa Margarita, CA (US); Michael T. Lotze , Pittsburgh, PA (US) | (56) References Cited U.S. PATENT DOCUMENTS |
| (73) Assignee: Invance Biotherapeutics, Inc. , San Carlos, CA (US) | 4,766,106 A 8/1988 Katre et al. 4,902,502 A 2/1990 Nitecki et al. 5,089,261 A 2/1992 Nitecki et al. 5,206,344 A 4/1993 Katre et al. 6,706,289 B2 3/2004 Lewis et al. 7,943,743 B2 5/2011 Korman et al. 8,008,449 B2 8/2011 Korman et al. 8,034,334 B2 10/2011 Dudley et al. 8,383,099 B2 2/2013 Dudley et al. 8,809,050 B2 8/2014 Vera et al. 8,956,860 B2 2/2015 Vera et al. 9,074,185 B2 7/2015 Dudley et al. 9,444,569 B2 12/2017 Gros et al. 10,671,717 A1 5/2020 Wilson et al. 9,525,590 A1 3/2011 Dudley et al. 1,362,228 A1 6/2011 Vera et al. 2,441,133 A1 9/2012 Rosenberg et al. 10,020,975 A1 4/2013 Vera et al. 11,561,617 A1 5/2013 Wilson 12,879,101 A1 11/2014 Bossard et al. 13,777,390 A1 12/2014 Welch et al. 2015/0175966 A1 6/2015 Vera et al. 2016/0010958 A1 1/2016 Gros et al. 2016/0208216 A1 7/2016 Vera et al. 2016/0215262 A1 7/2016 Powell 2017/0044496 A1 2/2017 Sarnak et al. 2017/0081635 A1 3/2017 Sarnak et al. 2017/0107490 A1 4/2017 Macurer 2017/0152478 A1 6/2017 Rosenberg et al. 2018/0127715 A1 5/2018 Veerapathran et al. |
| (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 201 days. This patent is subject to a terminal disclaimer. | |
| (21) Appl. No.: 15/863,634 | |
| (22) Filed: Jan. 5, 2018 | |
| (65) Prior Publication US 2018/0282694 A1 Oct. 4, 2018 | |
| | FOREIGN PATENT DOCUMENTS WO WO 2011/072088 A2 6/2011 WO WO 2012/065086 A1 5/2012 WO WO 2012/129201 A1 9/2012 WO WO 2013/057500 A1 4/2013 WO WO 2013/088147 A1 6/2013 (Continued) |
| | OTHER PUBLICATIONS U.S. Appl. No. 15/892,331, filed Feb. 8, 2018. (Continued) <i>Primary Examiner</i> — Michael A Belyavskiy (74) <i>Attorney, Agent, or Firm</i> — Morgan, Lewis & Bockius LLP |
| | (57) ABSTRACT The present invention provides improved and/or shortened methods for expanding TILs and producing therapeutic populations of TILs, including novel methods for expanding TIL populations in a closed system that lead to improved efficacy, improved phenotype, and increased metabolic health of the TILs in a shorter time period, while allowing for reduced microbial contamination as well as decreased costs. Such TILs find use in therapeutic treatment regimens. |
| (51) Int. Cl. C12N 5/06 (2006.01) A61K 35/17 (2015.01) A61K 38/20 (2006.01) A61K 31/675 (2006.01) A61K 31/7076 (2006.01) A61P 35/00 (2006.01) A61K 9/00 (2006.01) A01N 1/02 (2010.01) C12N 5/078 (2010.01) C12N 5/0783 (2010.01) | 46 Claims, 138 Drawing Sheets Specification includes a Sequence Listing. |
| (52) U.S. Cl. CPC A61K 35/17 (2013.01); A01N 1/0284 (2013.01); A61K 9/0019 (2013.01); A61K 31/675 (2013.01); A61K 31/7076 (2013.01); A61K 38/2013 (2013.01); A61P 35/00 (2018.01); C12N 5/0634 (2013.01); C12N 5/0636 (2013.01); C12N 5/0638 (2013.01); C12N 2501/04 (2013.01); C12N 2501/2302 (2013.01); C12N 2501/2315 (2013.01); C12N | |

Major Requirements of a Patent 对专利的主要要求

- “Novel”: e.g., your invention is new, was not described in the prior art
- “创新性”：例如你的产品是新的，在现有技术中从未出现过。
- “Non-obvious”: e.g., the differences between your invention and prior art would not have been obvious to someone in that field
- “差异不明显”：例如你的发明和现有技术之间的差异对该领域的人来说是不明显的。
- Written support and enablement
- 书面支持和授权
 - Fully disclosure the invention in exchange of a monopoly so that the invention can be practiced by anyone after expiration
 - 充分公开发明，以换取垄断权，使发明在到期后可由任何人实施。

What is Prior Art? 什么是现有技术？

Prior art includes: patents, printed publications, and other disclosures in the field of your invention that have been published before your effective filing date.

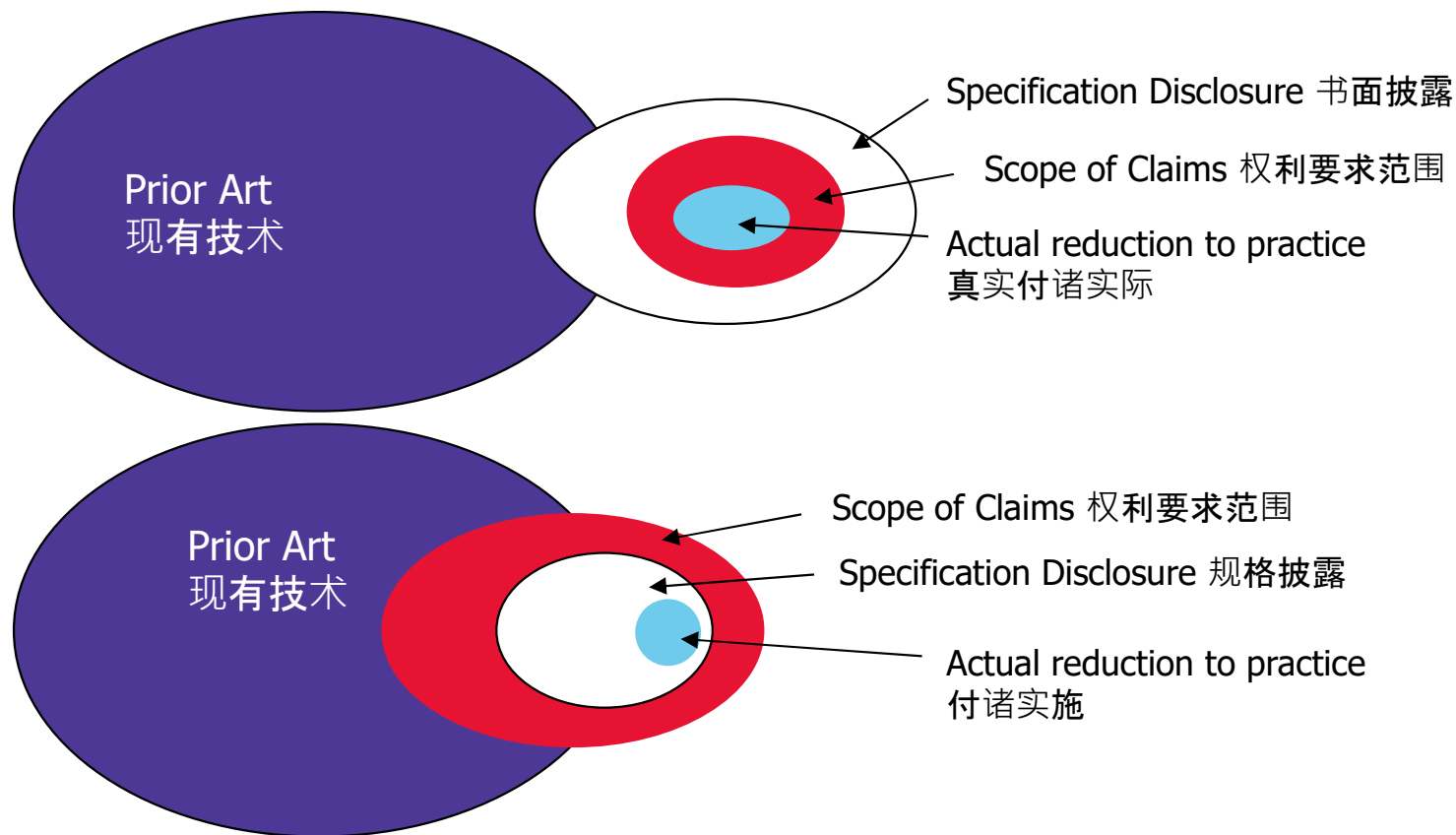
现有技术包括：专利、印刷出版物和在你的有效申请日期之前已经公布的、你的发明所属领域的其他披露信息。

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Breadth of Claims vs. Supporting Disclosure

权利要求的范围与支持性披露



What do I need to disclose? 需要披露什么？

A patent is a *quid pro quo*: 专利是一种交换条件：

- In exchange for 用于交换
 - The right to exclude others from making, using, importing, or selling your invention for a limited time period,
 - 在有限时间内排除他人制造、使用、进口或销售你的发明的权利
- You must fully disclose your invention so the public can benefit from it and expand on it.
- 你必须完全公开你的发明，以便公众能够从中受益，并对其进行扩展。

What do I need to disclose? 需要披露什么？

Slide 1 of 2

Does the disclosure:

- Demonstrate that the inventor was in possession of the claimed invention?
- Teach one of ordinary skill to make and use the invention without undue experimentation?
- Describe the best mode contemplated for carrying out the invention by the inventor?

披露的内容是否：

- 表明发明人拥有所述的发明？
- 教导普通技术人员在不进行不适当的实验的情况下制造和使用该发明？
- 描述了发明人为实施该发明所设想的最佳模式？

What do I need to disclose? 需要披露什么？

Slide 2 of 2

Are the claims clear enough that:

- The public is informed of the boundaries of your invention?
- It can be determined whether the claimed invention meets all the criteria for patentability?

权利要求是否足够清楚，以至于：

- 公众能够明确了解你的发明的界限？
- 可以确定所述发明是否符合专利的所有标准？

Trade Secret Basics 商业秘密概述



What is a Trade Secret? 什么是商业秘密？

- INFORMATION 信息
- Under Uniform Trade Secrets Act (UTSA), "Trade secret" means information, including a formula, pattern, compilation, program device, method, technique, or process, that:
- 根据《统一商业秘密法》(UTSA), "商业秘密"是指包括公式、图案、汇编、程序装置、方法、技术或工艺在内的信息, 它:
 - derives independent economic value, actual or potential, from not being generally know to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and
 - 由于不被其他人普遍知晓, 也不容易通过适当的方式确定, 而获得独立的经济价值, 实际的或潜在的, 可以从其披露或使用中获得经济价值, 并且
 - is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.
 - 为保持其机密性所做的努力是合理的。

Information That May Be Trade Secret

可能成为商业秘密的信息

- Formulas
- Recipes
- Source code
- Compilations
- Methods
- Techniques
- Prototypes
- Designs
- 配方
- 食谱
- 源代码
- 编排
- 方法
- 技术
- 原型
- 设计
- Business strategies
- Marketing plans
- Specifications
- Scientific data
- Financial data
- Customer lists and data
- Compilations of information
- 商业战略
- 营销计划
- 规格
- 科学数据
- 财务数据
- 客户名单和数据
- 信息的汇编

Many Businesses Rely Upon Trade Secret Protection

许多生意都依赖于商业秘密保护

- Relatively inexpensive to obtain protection (but there is cost of implementing trade secret programs? maintaining? enforcing?)
- 获得保护的相对成本较低（但有实施商业秘密项目的成本，维护和执行的成本？）
- Unlimited duration so long as secrecy is maintained (double-edged sword) and not independently created
- 只要保密性得到维持（双刃剑），并且不是独立创造的，就有无限的时间。
- But, no protection against independent creation (e.g., reverse engineering)
- 但是，对于独立创造（例如，逆向工程）没有保护。
- Well-known example: recipe for Coca-Cola; manufacturing know-how
- 众所周知的例子：可口可乐的配方；制造技术

How Can You Protect Your Proprietary Information Through Trade Secrets? 如何通过商业秘密保护你的专有信息？

Implement Confidential and Trade Secret Protection Program, including: 实施保密和商业秘密保护计划，包括：

- Require reasonable protection measures 要求采取合理的保护措施
- Employee agreements 雇员协议
- Confidentiality designations 保密性要求
- Employee training 员工培训
- Documentation of significant trade secrets 重要商业秘密文件归档
- Computer security and electronic and paper document control policy 计算机安全和电子及纸质文件控制政策
- Vendor, customer agreements 供应商、客户协议
- Disclosure, publication policies 披露、公开政策
- General security measures (e.g., restricting access to facilities and information) 一般安全措施（例如，限制对设施和信息的访问）
- Employee exit procedures 员工离职程序

What Are “Reasonable Measures”?

什么是“合理的保护措施”？

- Reasonable does **not** equal “extraordinary”
- “合理”不等于“特殊”。

- Every business does not need to implement the same measures for protection
- 每个企业不需要实施相同的保护措施。

- Nature of the trade secrets and of the business will impact assessment of whether measures are reasonable
- 商业秘密和企业的性质将影响对措施是否“合理”的评估。

- Not all unprotected disclosures destroy trade secret protection, but must take reasonable steps to cure
- 并非所有不受保护的信息披露都会破坏商业秘密的保护，但必须采取合理的措施来纠正。

- BUT failure to establish and observe reasonable measures will result in lack of trade secret protection
- 但未能建立和遵守合理的措施将导致缺乏商业秘密保护。

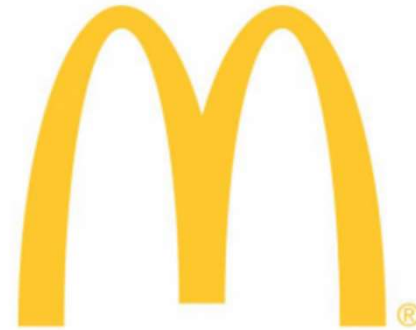
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What is a Trademark? 什么是商标？

- A trademark is a word, name, symbol or device which is used in trade with goods to indicate the source of the goods and to distinguish them from the goods of others.
- Trademark rights may be used to prevent others from using a confusingly similar mark, but not to prevent others from making the same goods or from selling the same or similar goods or services under a clearly different mark.
- 商标是一种文字、名称、符号或装置，在商品贸易中用于表明商品的来源并将其与他人的商品区分开来。
- 商标权可用于防止他人使用混淆性的类似商标，但不能用于防止他人制造相同的商品或以明显不同的商标销售相同或类似的商品或服务。

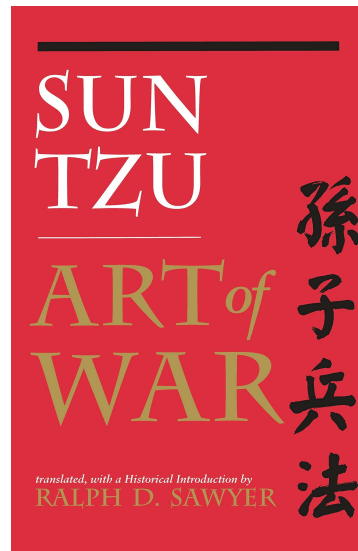


for "automobiles."



What is a Copyright? 什么是版权？

- Copyright is a form of protection provided to the authors of “original works of authorship” including literary, dramatic, musical, artistic, and certain other intellectual works, both published and unpublished.
- 版权是向“原创作品”的作者提供的一种保护形式，包括文学、戏剧、音乐、艺术和某些其他智力成果，包括已出版和未出版的作品。



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Intellectual Property Licenses 知识产权的许可证

- Permission to exercise patent rights – a permission to make, use, offer for sale, sell or import a patented invention.
- 行使专利权的许可--允许制造、使用、提供销售、销售或进口一项专利发明

- Permission to use a trade secret or trademark
- 使用商业秘密或商标的许可

- Permission to reproduce a copyrighted work
- 复制版权作品的许可

- Can be a significant source of revenue
- 可以是一项重要的收入来源

EVERYONE HAS A ROLE IN CREATING, STRENGTHENING, AND PROTECTING INTELLECTUAL PROPERTY

在创造、加强和保护知识产权方面人人有责

PLM R&D Solutions Marketing Sales Legal

产品生命周期管理 研发 解决问题 市场营销 销售 法律

IP Initiation
知识产权的发起



Prosecution
起诉



Protection/
Management
保护/管理



| | | | | | |
|--|--|--|--|--|---|
| | Submit disclosure 提交申请信息 | | Continuously update the disclosure 不断更新披露的信息 | | Promotion of patented features and benefits 宣传专利的特征和优势 |
| | Provide feedback on what the market likes 提供市场偏好的反馈 | | Report who is imitating/ taking ideas 报告发明人/提出者 | | Provide info on imitators 提供发起人的信息 |

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Biography



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- Deping Chai, a partner in Philadelphia office, focuses his practice on prosecuting patent applications in the life sciences, chemistry, and materials science industries. He counsels clients on international patent prosecution, due diligence, invalidity, and freedom to operate opinions. Deping also advises clients on clinical service agreements and sales contracts.
- Drawing on his technical background in chemistry and about 10 years of research experience in a leading pharmaceutical company, Deping helps clients secure and leverage patents for a wide variety of technologies, including small molecule drugs, formulations, and antibodies. Pharmaceutical clients turn to Deping for patent strategy and to protect their most important and innovative assets.
- 柴德平是费城办公室的合伙人，专注于处理生命科学、化学和材料科学行业的专利申请。他就国际专利申请、尽职调查、无效和可行性向客户提供咨询服务。柴律师还就临床服务协议和销售合同向客户提供建议。
- 柴律师凭借其化学技术背景和在世界著名制药公司约 10 年的研究经验，帮助客户保护和利用各种技术的专利，包括小分子药物、制剂和抗体。制药客户向柴律师咨询专利策略并保护他们最重要的创新资产



Biography



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Shon Lo is an effective, versatile litigator with trial experience that spans the gamut of intellectual property infringement actions, including patent, trademark, copyright infringement, and trade secret misappropriation in federal district court and before the International Trade Commission (ITC). Shon has particular experience in representing biotech and pharmaceutical companies in patent litigation, including matters arising under the Hatch-Waxman Act.

Shon Lo 是一位高效、全能型的诉讼律师，其审判经验涵盖联邦地区法院和国际贸易委员会 (ITC) 的知识产权侵权诉讼，包括专利、商标、版权侵权和商业秘密盗用。Shon 在代表生物技术和制药公司处理专利诉讼方面具有特殊经验，包括根据 Hatch-Waxman 法案。

Shon's matters for generic and branded pharma and biotech companies involve both large and small molecule products including Dupixent®, Repatha®, Praluent®, Sernivo®, Toviaz®, and Nuvigil®, among others. Shon particularly enjoys advising clients about the patent, regulatory, and antitrust issues that arise in the context of pharmaceutical product development and subsequent litigation. Shon is a registered patent attorney and conducts patent and trademark opinion work, counseling, and prosecution. She also conducts due diligence supporting corporate transactions.

Shon 为仿制药和品牌制药和生物技术公司处理的事务涉及大分子和小分子产品，包括 Dupixent®、Repatha®、Praluent®、Sernivo®、Toviaz® 和 Nuvigil® 等。Shon 擅长就医药产品开发和后续诉讼中出现的专利、监管和反垄断问题向客户提供建议。Shon 是一名注册专利代理人，从事专利和商标意见工作、咨询和起诉。她还可为公司交易进行尽职调查。

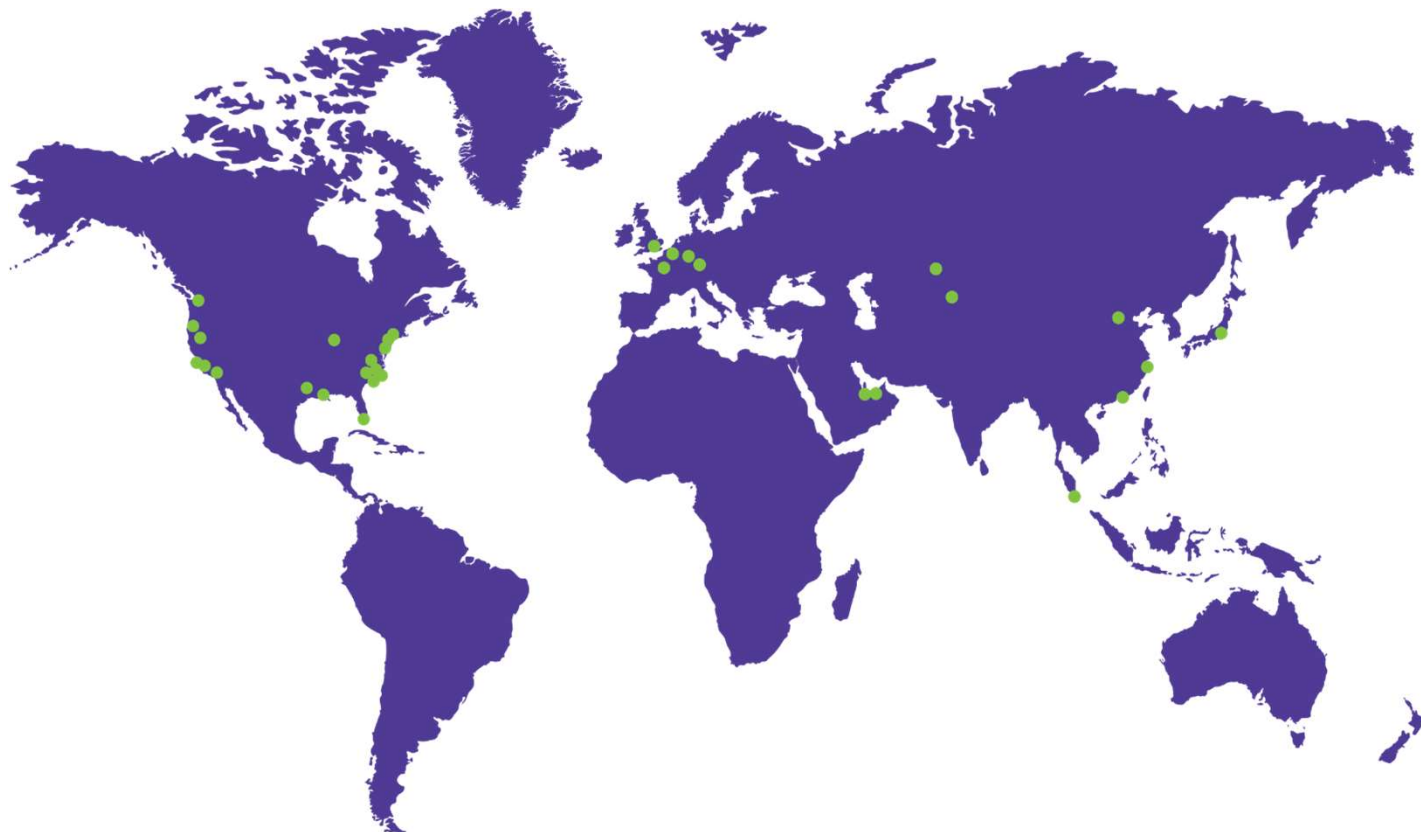
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