China Life Sciences
中国生命科学通讯 Newsletter

Welcome to the Fall/Winter 2012 issue of our China Life Sciences Newsletter, a periodic update on key developments, companies, and people in the dynamic China life sciences industry. In this issue, we bring you an interview with Dr. Dan Zhang, Founder and CEO of Fountain Medical Development, a full-service clinical CRO, based in South East Asia and China; the second of a three-part series discussing the strategic partnerships between Western and Chinese companies for the purpose of conducting early-stage pharma and biotech R&D (please find the first part in our Spring Issue); an analysis of compulsory patent licensing practices in China; and a discussion of new developments on the "patentable subject matter" requirement of U.S. patent law.

欢迎阅读本所2012年秋/冬季《中国生命科学通讯》！《通讯》定期报道中国生机勃勃的生命科学行业内的主要动态、公司及人物。本期包括以下内容：对方恩医药发展有限公司创始人及首席执行官张丹博士的访谈（方恩是一家位于东南亚和中国的提供全方位临床开发服务的CRO（新药开发外包服务组织））；关于中国和西方公司为进行药物和生物技术前期研发进行战略合作系列讨论的第二部分（共分三部分，第一部分请见我们的春季通讯）；对中国强制专利许可实践的分析；以及对美国专利法"可专利标的物"有关最新动态的讨论。

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Investor Q&A

Profile: Dr. Dan Zhang, Founder and CEO, Fountain Medical Development

Interview by Sue Xu

Dr. Dan Zhang has more than ten years of drug development experience. He is the Chief Executive Officer of Fountain Medical Development, a full-service clinical CRO company based in South East Asia and China. Previously, Dr. Zhang was the head of clinical development and global safety assessment at Sigma-Tau Research Inc., a Vice President at the Quintiles Transnational Corp., and the Chairman of the Board at Quintiles Medical Development (Shanghai) Company Ltd.

Over the last ten years, Dr. Zhang has established a strong working relationship with government and academic institutions in China. He chairs the GCP Grant Review Committee for the National Key Drug Development Program of the 12th Five-Year Plan, and is a consultant to the Center of Drug Evaluation of the State Food and Drug Administration. He was a member of the Overseas Expert Committee on New Drug R&D for the Ministry of Science and Technology of China and also served on the board of directors of Bayhelix.

Dr. Zhang received his pre-med training from Peking University and his M.D. from Peking Union Medical College. He continued his studies at the Harvard School of Public Health and received an M.P.H. in health policy and management. Then he continued his training at the Wharton Business School of the University of Pennsylvania, where he obtained his master's degree in healthcare management in 1998 and is working on his Ph.D. dissertation in the field of health economics and finance.

Q1: As both a clinician and an economist, you established one of the most recognized clinical CROs in the Greater China area. In fact, Fountain Med was awarded the "most promising company" award at the 4th ChinaBio Investor Forum. What were the unique opportunities you saw that inspired you to become an entrepreneur? Why China?

A: Exposure to business training and also opportunities in China encouraged me to become an entrepreneur in the Chinese market. I had a startup company before Fountain Med in China in 2000, which was equivalent to WebMD. That only lasted for half a year due to the global downturn, then I returned to the U.S. I started Fountain Med for several different reasons. At that time, I believed there would be a huge future demand for clinical CRO in China, which forced me to seriously consider starting such a business as Fountain Med with my co-founders who all had extensive senior management experience in major global pharmaceutical or CRO firms.

Q2: Things in China can change quickly, so can you provide an update of where your company has been heading and what it has been specifically focused on in the past couple of years? How is the growth of the company?

A: The past two years have really been our growth phase. Fountain Med is currently expanding geographically to more cities in China, and also in East Asia, including Hong Kong, Taiwan, and the South Korea market. We plan to penetrate to more markets in South East Asia so we can become a leading company in the whole region.

Another strategy independent of geographic penetration is naturally for us to maintain our world-class quality. We assist international clients, working with our partners from all over the world on high-quality healthcare, and using top of the line software. For us, world-class quality is always the standard by which to grow our business.

Q3: China has the largest population in the world, and its consumer markets are growing at a tremendous rate. Do you see more drugs pursuing clinical trials first in China? Will this be a trend?

A: Yes. We do see many more global giants coming to China to set up research and development centers. This has happened for multiple reasons. First, China's economy is still growing, so China's pharmaceutical market size will soon surpass Japan and become the second largest after the U.S. The global giants are looking toward future markets, so developing drugs that fit this market is important to them. The second reason is cost-effectiveness. Every year, there are lots of well-trained science major graduates, whose salaries are relatively low compared to those in the U.S. Last but not least, there have been more and more CROs like us who have grown successfully in China. For example, WUXI AppTec has become a global player based in China for the pre-clinical CRO industry. This has been encouraging for us, and we believe we can do the same thing in the clinical CRO industry. Therefore, this trend will really give us opportunities to work with global Big Pharma.

There are definitely more drugs that will pursue clinical trials first in China, not anywhere else, for two reasons. First, as I indicated before, more companies will consider developing products specifically targeting the China market, such as hepatitis, oncology, diabetes, cardiovascular diseases, stroke, and autoimmune disease products. Second, the Chinese government has invested heavily in the biotech sector in the last five years. Those investments will soon turn into first-in-man studies in China.

Q4: At present, the time required for regulatory review and approval of a clinical trial application (CTA) is a major consideration for companies deciding whether or not to conduct a clinical trial in China. It typically takes over 10 months for the SFDA to approve a CTA versus 30 days with the FDA. What advice would you give companies that wish to apply for a CTA to minimize any delays? Is the China SFDA planning to improve the current process and decrease the timeline?

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个人简介：方恩医药发展有限公司创始人兼首席执行官张丹博士

采访人：徐霄羽

张丹博士有着十多年的医药开发经验，现任方恩医药发展有限公司首席执行官，这是一家基于东南亚和中国的旨在提供全方位服务的临床CRO企业。张博士曾任希格玛托研究公司临床发展与全球安全评估主管、昆泰跨国公司副总裁、昆泰医学发展（上海）有限公司董事长。

在过去10多年间，张博士与中国政府和学术机构建立起牢固的工作关系。他担任第12个五年计划全国重点药物开发计划临床试验研究中心拨款审查委员主席和国家食品药品监督管理局药品评估中心顾问。以前曾经担任中国科学技术部新药研发海外专家委员会委员和百华协会董事会成员。

张博士在北京大学攻读医学专业，获得北京协和医学院医学博士学位。然后前往哈佛大学公共卫生学院继续深造，并获得卫生政策与管理硕士学位。之后，在宾夕法尼亚大学沃顿商学院继续求学，于1998年获得医疗管理硕士学位，目前正在准备有关卫生经济学和金融学的博士论文。

问题1： 作为临床医生和经济学家，你创立了大中国区最著名的临床CRO公司之一。实际上，方恩公司在第4届ChinaBio投资者论坛上被授予“最有前途公司”奖。你认为你发现了哪些独特的机会促使你成为一名企业家？为什么是在中国？

答：鉴于我所接受的商业培训和在中国存在的机会，这些都鼓励我成为中国市场上的一名企业家。在方恩公司之前，我曾经在中国2000年成立过一家创业公司，是一家相当于 WebMD的企业。但是由于全球经济衰退，公司仅仅存续了半年时间。然后，我回到美国。我创办方恩公司是出于几个原因。那时，我认为未来对于中国临床CRO的需求将会非常巨大。这促使我认真考虑和各位共同创办人一起发起一家类似方恩医药发展有限公司这样的企业。这些创办人全都具有在主要的全球性医药或CRO公司担任高级管理职务的经历。

问题2： 在中国，情况的变化可以用瞬息万变来形容。你能否谈谈在过去两年里，你的公司的最新发展状况？具体重点是什么？公司的增长情况如何？

答：过去两年的确是我们公司的成长阶段。方恩医药目前正在实施地理扩张，进入更多的中国和东亚城市，包括香港、台湾和韩国市场。我们计划渗透到东南亚的更多市场。这样我们就能够变成整个地区的龙头公司。

独立于地理渗透之外的另一项战略自然就是我们要保持世界一流的质量。我们与来自世界各地的合作伙伴一起利用顶级软件协助国际客户提供高质量医疗保健服务，对于我们来说，世界级的质量始终是我们实现业务增长时所遵循的标准。

问题3： 中国拥有世界上最多的人口，其消费者市场正在以惊人的速率增长。你是否看到有更多的药物来中国进行临床试验？这是否会成为一种趋势？

答：是的。我们的确看到有越来越多的全球巨头来中国设立研发中心，这背后有着多种原因。首先，中国经济仍在增长。因此，中国的医药市场规模很快就将超越日本，成为仅次于美国的全球第二大市场。全球巨头都着眼于未来市场，所以，开发适合于该市场的药物对于他们来说至关重要。第二个原因是成本效益。每一年都有大批受过良好教育的科学专业学生毕业，他们的薪酬与美国相比很低。最后但同样重要的一个原因是，有越来越多像我们公司这样的临床CRO企业在中国实现了成功的发展。例如，无锡药明康德已成为位于中国的临床前CRO行业的全球供应商。这对我们来说是个莫大的鼓舞。我们认为我们能够在临床CRO行业做同样的事情。因此，这个趋势将会给我们机会来与全球制药巨头合作。

肯定会有更多药物首先会在中国寻求进行临床试验，而不是别的什么地方。原因有两个。首先，我刚才说过了，有更多公司考虑开发专门面向中国市场的产品，例如针对肝炎、肿瘤、糖尿病、心血管疾病、脑卒中和自体免疫性疾病的产品。其次，中国政府过去五年在生物科技领域投入巨资。这些投资将很快转为在中国进行的首次人体作用研究。

问题4：目前，各家公司在决定是否在中国进行临床试验时，监管部门对临床试验申请（CTA）进行审批所

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Q&A

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A: The Chinese government has done several things to speed up the approval process. First, in 2009, there was a new policy that allowed accelerated approvals, called the Special Handling Procedure (SHP). SHP can help a company speed up its application time for IND CTA from 8-12 months to 6-8 months. In my opinion, the Chinese government will continue to shorten the application period.

On the other hand, you cannot compare apples to oranges. It takes normally one month for the FDA to approve the CTA application, but much longer to get IRB (Institutional Review Board) approval. However, if you compare the time period spent from filing the CTA to having the first patient in, China has no delay compared with the U.S. at all. You should not just see one aspect and let the CTA prevent you from conducting clinical trials in China, but strategically plan your product development with all aspects considered.

Q5: What is the likelihood of approval for a CTA to perform a first-in-man Phase I study in China?

A: Currently, only domestic firms are allowed to do a first-in-man study in China, but we do see more and more international firms collaborating with domestic firms, which are the major applicants for Phase I studies. This is one way of getting first-in-man studies done in China. Furthermore, there are internal discussions within SFDA about the possibility of allowing first-in-man studies in selected therapeutic areas, such as oncology, to be performed by international firms. However, we don't know whether this will happen anytime soon.

Q6: When designing a global product registration strategy, companies may wish to consider incorporating regulatory requirements for eventual China market approval. What are the regulatory requirements for product approval in China if a global trial is conducted that includes patients from China? Is there precedence when a new therapeutic product is approved first in China? What are the key considerations for designing a global registration trial that includes patients from China? How can small companies without resources in China design such a global product registration strategy?

A: I would suggest our clients, especially U.S. clients, include China as a part of their global drug development planning. Such a strategy makes it possible to hit three birds with one stone. Our clients can use data from China to support future SFDA filings, China data can also be used to file U.S. and Europe CTAs, and last but not least, China data can be used to support Japanese filings as well.

This is very important during the early and late phases of development. When you involve China as a site to obtain enough Chinese patients, the data from Chinese patients will not only support global applications, but also speed up your future Chinese CTA. Because you've already had enough data from Chinese patients in your global trials, the Chinese SFDA might waive the additional trial requirements for China registration.

We've been working with lots of small and even virtual American companies to help them register products in China for clinical trials. Many of our clients register their products first in China, and they build manufacturing lines in China before making their application, to support China registration. Alternatively, they can consider getting FDA approval in the U.S. or Europe first, and then setting up one phase of importation trials to get Chinese SFDA approval for importation. In this case, you can keep your manufacturing line outside of China.

Q7: Fountain Med and ICON Central Lab signed an alliance deal two years ago. What are the reasons behind such alliance?

A: ICON has quite extensive operations in the U.S. and Europe, while Fountain has a larger operation than many global CROs and domestic firms in China. This is absolutely a win-win collaboration. It will help clients in the U.S. and Europe, who are very familiar with ICON's service, get our quality service when they come to China.

Q8: Many global CROs have significantly expanded their capabilities for lab testing in China for their strategic partners, and they bring a recognized brand, a client base, and experience. What is your vision of such a trend? How do local firms differentiate themselves from global giants?

A: This is a very good question. CROs like us are very strong in East Asia and China, and I think we have advantages over the global CROs. We have more intimate and local knowledge, and we have a much stronger working relationship with the Chinese SFDA and local regulators. In addition, we respond fast, and we have competitive prices.

This partially comes from the strong government relationship that we have developed. For example, our company works closely with SFDA for technical guideline development. In addition, I myself am also involved with the training of SFDA medical reviewers. The SFDA asked us to provide training to the pharmaceutical industry about how to communicate with SFDA efficiently, due to our strong relationship and high credentials. Fountain Med received the 2010 "Outstanding Service Award" awarded by SFDA. Such achievements would be very difficult for any CRO, including global CROs.

Q9: How do you get employees who speak English and have the same level of customer service as in the U.S.? How do you retain high-quality staff?

A: One important thing for a local firm like us is to provide more career development opportunities for employees. When you work for a big firm, the development potential is somewhat limited because big firms tend to have precise career ladders. Second, we

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个人简介

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需的时间成为一个主要考虑因素。国家食品药品管理局一般需要10个多月时间来审批一项，相比之下美国食品药品管理局只需30天。对于想申请CTA的公司你会给出什么建议来最大限度减少任何延误？中国药监局是否打算改进现有程序，来缩短时限？

答：中国政府采取了几项措施来加快审批程序。首先，在2009年，出台了一项新政策，叫做特别处理程序，允许加快审批。该程序可以帮助一家公司缩短IND CTA的申请时间，从8-12个月减少至6-8个月。在我看来，中国政府将会继续缩短申请期限。

另一方面，你不能拿苹果去和橘子比。美国食品药品管理局通常只需一个月时间来批准CTA申请，但是获得IRB（机构审查委员会）批准的时间却要长得多。不过，如果你比较从提出CTA到用于第一个患者所花的时间，中国与美国相比完全没有任何拖延。你不应当只看到一个方面，使得CTA妨碍你在中国进行临床试验，而是应当从战略角度策划你的产品开发，考虑所有方面。

问题5： 在中国进行首次人体作用一期研究的CTA获得批准可能性有多大？

答：目前，只允许国内公司在中国进行首次人体作用研究，但是我们的确看到有越来越多的国际公司在与国内公司合作，这些国内公司是一期研究的主要申请人。这是在中国开展首次人体作用研究的一种方法。此外，药监局正在进行内部讨论，看看是否可能允许外国公司在选定的治疗领域进行首次人体作用研究，例如肿瘤疾病。但我们不知道这是否很快就会施行。

问题6：在设计全球产品注册战略时，公司可能希望考虑将适用于中国市场最终审批的监管要求包括进来。如果进行包括中国患者在内的全球试验，中国的产品审批监管要求都有哪些？一种新的医疗产品首先在中国获得审批，这是否有先例？设计包括中国患者在内的全球注册试验，有哪些关键考虑因素？在中国没有资源的小公司如何设计此类全球产品注册战略？

答：我会建议我们的客户，特别是美国客户，将中国作为他们全球药品开发策划的一部分。这样的战略才可能收到一石三鸟的效果。我们的客户可以用中国的数据 来支持未来向药监局提出的申请。此外，中国的数据还可以被用来向美国和欧洲提出CTA。最后但同样重要的一点是，中国的数据同样可以用来支持向日本提出申请。

在开发的早期和后期阶段，这是非常重要的。把中国作为一个获得足够中国患者的场所后，来自中国患者的数据将会不仅支持全球申请，而且可以加快你未来在中国的CTA。由于在你的全球试验中已经有了足够的来自中国患者的数据，因此中国药监局可能放弃对在中国注册提出额外的试验要求。

我们一直与很多小型甚至是虚拟的美国公司合作，帮助他们在中国注册产品用于临床试验。我们的很多客户都首先在中国注册自己的产品。他们在提出申请之前就在中国建造生产线，来支持在中国的注册。或者，他们可以考虑先在美国或欧洲获得食品药品管理局的批准，然后进行一个阶段的进口试验，来获得国家药监局的进口批准。在这种情况下，你可以保留在中国境外的生产线。

问题7：方恩公司和ICON中央实验室两年前签署了联盟协议。这个联盟背后的原因是什么？

答：ICON在美国和欧洲拥有广泛的经营业务，而与很多全球CRO和国内公司相比，方恩公司在中国拥有更大的业务规模。这绝对是一种双赢协作。它帮助十分熟悉ICON服务的美国和欧洲的客户来到中国时能够得到我们的高质量服务。

问题8：很多全球CRO企业为了自己的战略合作伙伴都显著地扩展了它们在中国的实验室试验能力。它们带来了知名品牌、客户群和经验。你怎么看待这一趋势？本地公司如何在与全球巨头的竞争中确立差别优势，在市场中占据一席之地？

答：这是个很好的问题。像我们公司这样的CRO在东亚和中国都很强大。我想我们比全球性CRO企业更具优势。对于本地情况我们有更加深入的了解。我们与中国药监局和当地监管部门的工作关系要更为牢固。此外，我们具备迅速的响应能力，价格上也更具竞争性。

这一优势部分体现在我们已经建立起来的强大的政府关系。例如，我们公司在技术准则的制定方面与国家药监局密切配合。此外，我自己也参与了对国家药监局医药审查员的培训工作。国家药监局要我们就如何有效地与药监局沟通向制药业提供培训，因为我们有着紧密的关

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Q&A

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offer more opportunities to our employees to work on international projects, and they can get product-based training as well. Last but not least, we offer competitive salaries to retain high-quality employees.

Q10: We would be interested to know what gets you up every morning, and makes you excited about Fountain Med.

A: The most exciting thing for me is to see that Fountain Med has continuously enjoyed a rapid growing phase, with more interesting projects, penetrating more in South East Asian markets, obtaining more partners in India, Europe, and the U.S. I believe in this business.

Dr. Xiaoyu (Sue) Xu is a postdoc fellow at Stanford University, where she studies skin stem cells and hair regeneration. She's published more than ten journal papers and filed three US. patents in the field of small molecule inhibitors for cancer treatment and protein therapy for skin diseases. Sue currently serves as a coordinator at the Chinese American Biopharmaceutical Society (CABS) Office of Operations.

Key Regulatory Issues for Strategic Life Sciences Partnerships in China

By Can Cui, Thomas Chou, and Gordon Milner

In the first installment of this series of three articles, we presented an overview of the drivers behind the recent trend toward entering into strategic partnerships in China, and a high-level summary of the best practices to consider when contemplating such a relationship.

In this second article we take a more granular look at some of the key legal and regulatory issues entities face when negotiating arrangements with strategic partners in China, whether in the form of a simple standalone technology license, or as part of a more complex joint venture relationship, with particular regard to technology import rules, restrictions on foreign investments, intellectual property protection, and tax implications.

In our next issue we will look at some of the more complex structures by which strategic partnerships can be implemented, and how such relationships can be structured to avoid or at least mitigate some of the issues discussed in this article.

Many of the commercial issues that arise when negotiating strategic partnership arrangements in China are similar to those faced when contracting with strategic partners in other jurisdictions. However, China's extensive and multi-layered regulatory regime can place significant fetters upon the structures and commercial accommodations that are commonly used to address those issues in other jurisdictions, and must be taken into account when contemplating any strategic partnership there.

Technology Licenses

Technology licenses, whether for patented active compounds, medical databases, or manufacturing know-how, can be found at the heart of most cross-border strategic partnerships in the China life sciences sector. In some cases, the license is essentially the entire relationship; standalone commercial licenses under which the technology owner may earn royalties without the burden of establishing its own onshore business are commonplace. In other cases, the technology license forms just one aspect of a more complex relationship—for example, a joint venture in which the offshore technology owner takes an equity interest.

Restrictions on Technology Imports

As we noted in the last issue, one attractive and relatively unusual aspect of the Chinese market is the opportunity to marry Western products and technologies with Chinese partners and financial investment. Typically, strategic partnerships in China will entail the import of existing core technology by the offshore partner, whether by way of license or assignment.

While the import and distribution of APIs and finished products are typically tightly regulated in most countries, Western companies are often surprised by the extent to which the provision of underlying patents and know-how to China is also regulated. The import of technology into the PRC is primarily governed by the Regulations on Administration of Technology Imports and Exports, which came into effect on January 1, 2002 (the "TIE Regulations"). Technology imports are defined very widely and include, in addition to patent assignments and licenses, mere transfers of technical know-how and the provision of technical services. As such, the TIE Regulations will affect the vast majority of strategic partnerships for R&D in China.

The TIE Regulations divide technology imports into the categories of 'prohibited', 'restricted', and 'permitted'. The first two categories are defined by reference to a catalogue later amended and maintained by the PRC Ministry of Commerce ("MOFCOM").[1] Government approvals are required for the import of 'restricted' technologies, while, as the name suggests, 'prohibited' technologies cannot be imported into China. Any technology that is not included in either the 'prohibited' or the 'restricted' category is considered 'permitted'. 'Permitted' technologies may be imported only by registering the import contracts.

The TIE Regulations, together with the Administrative Measures for the Registration of Technology Import and Export Contracts (the "Administrative Measures"), impose several requirements upon the import of permitted technologies;

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个人简介

(续第5页)

系和很高的专业资质。方恩公司曾荣获国家药监局颁发的2010年度“杰出服务奖”。这一成就是多数CRO企业难以企及的，包括全球性CRO。

问题9：你如何招募到既能讲英语又能达到与美国相同水准的客户服务的员工？你是如何留住高素质员工的？

答：对于像我们这样的本地公司，很重要的事情是要为员工提供更多的职业发展机会。在为大公司工作时，发展潜力多少会受到限制，因为大公司往往都有严格的职业阶梯。其次，我们为员工提供更多参加国际项目工作的机遇。此外，他们还可以得到基于产品的培训。最后但同样重要的一点是，我们提供具有竞争力的薪酬来留住高素质员工。

问题10：我们很有兴趣想知道，每天早上是什么把你从梦中唤醒，是什么让你对于方恩的未来备感振奋？

答：最令我振奋的事情是看到方恩公司不断实现快速发展，获得更多有趣的项目，更加深入地渗透到东南亚市场，在印度、欧洲和美国争取到更多的合作伙伴。我对这个行业充满信心。

徐霄羽博士现任斯坦福大学医学院博士后研究员，从事皮肤干细胞和组织再生领域的研究。她在小分子抑制剂治疗癌症以及皮肤病蛋白疗法领域发表过十余篇学术论文，并拥有三份美国专利。徐霄羽博士同时担任北美华人生物医药协会（CABS）运营部项目经理。

在中国生命科学领域建立战略合伙伴关系的主要监管问题

作者：崔粲，周至恒，Gordon Milner

在三篇文章的第一篇中，我们对在中国建立战略合伙关系的最近发展趋势的推动力进行了全面概述，并扼要总结了在拟建立该等关系时可以考虑的最佳做法。

在本第二篇文章中，我们较详细的阐述在与中国战略合作伙伴磋商安排（无论是以简单的独家技术许可形式，还是作为更为复杂的合营关系中的一部分）时企业面临的主要法律和监管问题，尤其就技术进口规则、对外国投资的限制、知识产权保护以及课税影响做详尽的阐述。

在下一期中，我们将关注可用以实施战略合伙关系的更为复杂的结构，以及如何设定该等关系的结构以避免或者至少减少本文中讨论的某些问题。

在中国磋商战略合伙关系安排时产生的许多商业问题与在其他司法管辖区与战略合作伙伴订立合同时面临的问题类似。但是，中国全面、多级的监管制度对普遍用于解决其他司法管辖区中的该等问题的结构和商业适宜性施加了重要限制，而且在拟在中国建立任何战略合伙关系时必须考虑该等监管制度。

技术许可

技术许可（无论是针对受专利保护的活性成分、医疗数据库还是生产专有技术）经常是中国生命科学领域众多跨境战略合伙关系的核心内容。在某些情况下，许可本质上就是整个关系；技术所有人无需承担建立其自己境内业务的负担，就可以获得使用费的独立商业许可是十分普遍的许可。在其他情况下，技术许可仅构成更为复杂关系的一个方面 – 例如，境外技术所有人拥有之股权的合营公司。

对技术进口的限制

如我们在上期中提到的，中国市场具有吸引力的且相对不平常的一个方面就是为西方产品和技术与中国合作伙伴和金融投资的结合提供了机会。典型情况下，在中国建立战略合伙关系会使境外合作伙伴通过许可或转让方式进口现有核心技术。

虽然典型情况下多数国家对进口和经销原料药和成品均进行严格监管，但西方公司经常对向中国提供有关专利和专有技术也受到监管的范围表示惊讶。将技术进口到中国主要受于2002年1月1日生效的《技术进出口管理条例》（“技术进出口管理条例”）规管。技术进口的定义较为广泛，除了专利转让和许可外，还包括单纯的专有技术转让以及提供技术服务。因此，技术进出口管理条例将影响中国研发领域的绝大多数战略合伙关系。

技术进出口管理条例将技术进口分为‘禁止’、‘限制’、‘许可’三类。前两类的定义参照了之后由中国商务部（“商务部”）修订并维持的目录。[1] 进口‘限制’类技术需获得政府批准，同时如名称所示，‘禁止’

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Key Regulatory Issues

(Continued from Page 6)

these requirements can be particularly onerous on the offshore party:

- The import agreement must be registered with MOFCOM within 60 days of execution. Documents filed must be translated into Chinese if they were executed in English;
- The import agreement must include a warranty of IP non-infringement from the offshore party;
- The import agreement must include a warranty from the offshore party that the technology is 'complete, correct, effective, and capable of accomplishing the agreed technical targets'; and
- The license agreement must not restrict the Chinese party from making improvements to the technology. The IP in any improvements the Chinese party does make will vest in the Chinese party by operation of law.

Non-compliance with the TIE Regulations is fairly common, though typically this arises from ignorance of the existence of the TIE Regulations rather than from any party's intention.

Although the TIE Regulations do not expressly set out any penalties (monetary or otherwise) that would apply to the licensor or licensee of 'permitted' technologies (with the exception of fraud), non-compliance may give rise to several adverse consequences:

- *Difficulty Paying Fees*. The Chinese party may not be able to remit license or service fees or other forms of revenue share to the offshore party, because to do so lawfully, the Chinese party must present its bank with a MOFCOM registration certificate for the import agreement.
- *Possible Loss of IP Protection*. The import of any technology under arrangements that are not in compliance with the TIE Regulations is unlawful. As such, if the PRC courts consider a technology owner to have been a willing participant in a violation of the TIE Regulations, they may decline to grant discretionary remedies such as injunctive relief against both the Chinese party and infringing third parties in China. Furthermore, the PRC authorities are likely to decline to take administrative action to protect unlawfully imported IP.
- *Possible Loss of Contract Enforcement*. It is unclear whether a contract that violates the TIE Regulations would be enforceable by the PRC courts. Certainly any non-compliant provisions regarding improvements would be void. Moreover, injunctive relief to restrain any ongoing breach would likely be unavailable (see above).
- *Damaged Reputation with the PRC Government*. A foreign company that is found to have violated the TIE Regulations is likely to face increased difficulty when applying for future permits and approvals from the Chinese government.

It is important to note that the TIE Regulations are mandatory and will apply regardless of the choice of governing law in the import agreement. However, strategies do exist for avoiding or mitigating the adverse impact of the TIE Regulations while avoiding the consequences of non-compliance. For example, it may be possible to structure the arrangements so that the technology is provided to an offshore joint venture or affiliate of the Chinese party, which then imports the technology intra-group, or to provide the technology via an onshore affiliate of the offshore party (so that the technology import stage is wholly within the offshore party's group). We will explore these more complex structures in greater detail in our next issue.

Restrictions on Technology Exports

The TIE Regulations also regulate the export of technology from China and will apply to any assignment or license of patents and/or disclosure of know-how from the Chinese party (or onshore joint venture) to the offshore party. Accordingly, there is a catalogue specifying technologies that are prohibited or restricted for export, maintained by MOFCOM and the PRC Ministry of Science and Technology. Assuming that the exported technology does not fall within the catalogue, the Administrative Measures merely require that the export agreement (together with a Chinese translation) be registered with MOFCOM within 60 days of execution. The other requirements noted above with regard to import agreements do not apply to exports of technology.

Tax Implications

Under the PRC Enterprise Income Tax Law ("EIT Law"), license fees or other consideration payable by a Chinese licensee to a foreign licensor under a cross-border technology license is subject to Enterprise Income Tax levied on a withholding basis. The current tax rate applicable to technology licenses is 10% of the gross fees. Generally speaking, such license fees are also subject to a 5% PRC Business Tax, although certain types of technology transfer are eligible for an exemption from Business Tax. In some pilot locations, such as Shanghai and Beijing, Business Tax has recently been phased out and the scope of value-added tax ("VAT") expanded to include supplies previously covered by Business Tax. In Shanghai, for example, technology transfer services are part of the VAT pilot and subject to VAT instead of Business Tax. Depending on the annual turnover, a VAT taxpayer providing technology transfer services is subject to a VAT rate of 3% or 6%.[2] In addition, under the PRC Provisional Rules on Stamp Duty, technology transfer contracts are subject to PRC stamp duty, payable by each party to the contract at a rate of 0.03% or 0.05%, depending on the type of contract.[3]

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主要监管问题

(续第7页)

类技术不能被进口到中国。未包含在‘禁止’或‘限制’类中的任何技术被视为是‘许可’进口的技术。‘许可’类技术仅可以通过登记进口合同的方式进行进口。

技术进出口管理条例以及《技术进出口合同管理办法》（“管理办法”）对进口许可技术规定了若干限制；该等限制对外方而言尤为繁琐：

- 进口协议必须在签署后60天内在商务部进行登记。所提交的文件如果是以英文形式签署的，则必须翻译成中文；
- 进口协议中必须包含外方出具的未侵犯知识产权的保证；
- 进口协议中必须包含外方出具的保证，表明技术是‘完整、准确、有效的，且可以完成约定的技术目标’；以及
- 许可协议不得限制中方对技术作出改进。中方所实现的任何改进中的知识产权应依法归中方所有。

没有遵守技术进出口管理条例的情况是较为普遍的，尽管通常情况下是因不知道存在技术进出口管理条例导致的而不是因任何一方故意违反而导致的。

尽管技术进出口管理条例并未明确规定适用于‘许可’技术（欺诈除外）许可人或被许可人的任何处罚措施（金钱处罚或其他处罚），但未遵守该条例将产生一些不利后果：

- *难以付款。*中方可能不能向外方进行许可费或服务费或其他收益份额的汇款，因为若想合法汇款，其必须向其银行提供商务部对进口协议的登记证。
- *可能失去对知识产权的保护。*依照违反技术进出口管理条例的协议进口任何技术均是非法的。因此，如果中国法院认为某项技术所有人是自愿参与违反技术进出口管理条例的，那么他们可能拒绝向中方和中国侵权第三方授予自由裁量的弥补，如禁止令救济。此外，中国机构很可能拒绝采取行政措施保护非法引进的知识产权。
- *可能失去合同执行力。*违反技术进出口管理条例的合同是否可由中国法院强制执行尚不明确。但可以肯定的是任何不合规的关于改进的规定将是无效的。此外，很可能不能获得限制任何持续违约的禁止令救济（参见上文）。
- *损害了在中国政府的声誉。*被发现曾违反技术进出口管理条例的外国公司在向中国政府申请未来许可和批准时很可能面临更多困难。

知道技术进出口管理条例是强制性的且无论进口协议中选择哪个管辖法律技术进出口管理条例均将适用这一点是十分重要的。但是，在避免不合规的后果的同时，的确存在避免或减轻技术进出口管理条例不利影响的策略。例如，可以设计协议，以向中方的境外合营公司或关联公司提供技术，随后进口集团内部技术，或者可以通过外方的境内关联公司提供技术（因此技术进口完全是在外方的集团内部进行的）。我们将在下一期中更为详尽的阐述该等较为复杂的结构。

对技术出口的限制

技术进出口管理条例还规管着中国的技术出口并将适用于中方（或境内合营公司）向外方进行的任何转让或专利许可和/或专有技术披露。相应的， 商务部和中国科学和技术部保持有一份目录，规定了禁止或限制出口的技术。如果出口的技术不属于目录中规定的，管理办法仅要求在签署出口协议后60天内在商务部登记出口协议（连同其中文翻译）。以上关于进口协议的其他要求不适用于技术出口。

课税影响

根据《中国企业所得税法》（“所得税法”），中国被许可人根据跨境技术许可应向外国许可人支付的许可费或其他对价需缴纳以代扣方式征收的企业所得税。适用于技术许可的现行税率为总费用的10%。通常而言，该等许可费还需缴纳5%的中国营业税，尽管有些类型的技术转让有资格豁免缴纳营业税。在一些试点地区（如上海和北京），营业税最近已经被逐步取消，但增值税的范围扩大为包括之前营业税覆盖的用品。例如，在上海，技术转让服务是增值税试点的一部分而且需缴纳增值税而不是营业税。根据年营业额的不同，提供技术转让服务的增值税纳税人需缴纳3%或6%的增值税。[2] 此外，根据《中华人民共和国印花

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Key Regulatory Issues

(Continued from Page 8)

Technology transfer as a way of capital contribution to a Chinese company is not subject to PRC Business Tax. Technology licensing between two associated enterprises is often subject to close scrutiny by the Chinese tax authorities, however. Under the EIT Law, if a technology licensing transaction between an enterprise and its associated party does not comply with the arm's-length principle and results in a reduction in the taxable income or revenue of either party, the tax authorities may make adjustments under China's transfer pricing rules. Foreign companies are well-advised to retain adequate documentation justifying any transfer pricing if their royalty rates are set so high as to reduce the profits of their Chinese affiliates to a level unacceptably low to the Chinese tax authorities.

More Complex Partnering Structures

Recent years have seen many offshore technology owners seeking more active participation in their Chinese partnering arrangements than can be achieved under standalone technology license arrangements. Such participation will often involve the establishment of a joint venture vehicle in which the offshore party can acquire an equity interest. This vehicle may be an onshore Sino-foreign Equity Joint Venture ("EJV"), or an offshore joint venture company that owns an onshore operating entity in China. Such arrangements give rise to several additional regulatory concerns on top of those applying to simpler license structures.

Restrictions on Foreign Ownership

The ability of foreign-invested entities ("FIEs"—a term including both EJVs and wholly owned subsidiaries of offshore companies) to participate in Chinese industries is governed by the Industrial Catalogue Guiding Foreign Investments, now in its sixth edition, issued by the National Development and Reform Commission and MOFCOM in 2011 (the "Foreign Investment Catalogue"). The Foreign Investment Catalogue sets forth certain activities in which FIE participation is encouraged, restricted, or prohibited. Any activity that falls outside these three categories is generally considered to be permitted. There is no general prohibition on FIEs participating in the development, manufacturing, and distribution of pharmaceuticals or medical devices in China and indeed the manufacture of certain strategically important pharmaceuticals falls within the encouraged category of the Foreign Investment Catalogue. We highlight below the listings of some of the industries relevant to forming R&D strategic partnerships in the areas of pharmaceuticals and medical devices.

Restrictions on the Use of IP Assets as Capital Contributions

Capital funding rules in China are relatively inflexible. In order to acquire an equity interest in an EJV, the offshore party will need to contribute towards the

	Encouraged	Restricted	Prohibited
Pharmaceutical Industry	Production of new compound drugs or drugs with APIs (including crude drugs and formulations)	Production of chloramphenicol, penicillin G, jiemycin, gentamicin, dihydrostreptomycin, amikacin, tetracyn, oxytetracycline, mydecamycin, kitasamycin, ciprofloxacin, and ofloxacin	Processing of Chinese medicinal materials listed in the Regulation on the Protection of Wild Medicinal Resources and the Catalogue of China's Protected Rare, Precious, and Endangered Plants
	Amino acids: production of tryptophan, histidine, and methionine used in feed, etc., using zymotechnics		
	Production of new types of anticancer drugs, cardiovascular and cerebrovascular drugs, and nervous system drugs	Production of analgin, paracetamol, vitamin B1, vitamin B2, vitamin C, vitamin E, multivitamin formulations, and oral calcium formulations	
	Production of new types of drugs employing bioengineering and biotechnology		
	Production of HIV/AIDS vaccines, hepatitis C vaccines, contraceptive vaccines, and new types of vaccines for cervical carcinoma, malaria, and hand-foot-and-mouth disease, etc.	Production of varieties of vaccines included in the national immunity planning	
	Production of biovaccines		Application of processing techniques such as steaming, stir-frying, moxibustion, and calcination for making small pieces of ready-for-use traditional Chinese medicines; production of traditional Chinese medicine of secret prescriptions
	Development and production of marine drugs	Production of crude drugs for anesthetics and Category I psychotropic drugs (Chinese parties as controlling shareholders)	
	Pharmaceutical formulations: production of new formulations and new products employing new technologies, such as slow release, controlled release, targeting, and percutaneous absorption		

(Continued on Page 12)

主要监管问题

(续第9页)

税暂行条例》，技术转让合同需缴纳中国印花税，根据合同类型不同，合同的每一方应缴纳0.03%或0.05%的印花税。[3]

作为一种向中国公司进行资本出资方式的技术转让无需缴纳中国营业税。但是，两家关联企业间进行的技术许可通常受中国税务机关的严格监督。根据企业所得税法，如果一家企业与其关联方之间的技术许可交易不是按照公平原则进行的，导致任何一方的应纳税所得或收入减少，那么税务机关可能根据中国的转让定价原则进行调整。外国公司被告知保留适当的文件，以在其使用费订的较高以至于将其中国关联公司的利润降低到中国税务机关难以接受的低水平时，证明任何转让定价的合理性。

更复杂的合作结构

近年来，与独立技术许可安排相比，寻求更积极参与中国合作安排的境外技术所有人更多了。该等参与经常涉及建立据以外方可以收购股权的合资工具。该工具可以是境内中外合资经营企业（“合资企业”）或者在中国拥有境内运营实体的境外合资公司。该等安排引发了其他一些除了适用于简单许可结构外的监管问题。

对外国所有权的限制

外国投资企业（“外资企业”－包括合资公司和境外公司的独资子公司）参与中国产业的能力受国家发展和改革委员会和商务部于2011年发布的《外商投资产业指导目录》（“外资产业目录”；现行第六版）规管。外资产业目录规定了鼓励、限制或者禁止外国投资企业参与的某些活动。不属于这三种类别的任何活动通常被认为是允许的。对参与中国医药或医疗设备开发、生产和经销的外资企业并没有普遍禁止，而且实际上某些战略上重要的药品的生产在外资产业目录中是被鼓励的。以下为与在医药和医疗设备领域建立研发战略合伙关系有关的若干行业的清单。

知识产权资产出资限制

中国的资本融资制度相对不太变通。为取得合资企业的股权，外方需按其持股比例对合资公司注册资本出资。许多外方技术所有人倾向于将其技术和知识产权作价出资。尽管通常可以这么做，

	鼓励类	限制类	禁止类
医药制造业	新型化合物药物或活性成份药物的生产（包括原料药和制剂）	氯霉素、青霉素G、洁霉素、庆大霉素、双氢链霉素、丁胺卡那霉素、盐酸四环素、土霉素、麦迪霉素、柱晶白霉素、环丙氟哌酸、氟嗪酸生产	列入《野生药材资源保护条例》和《中国珍稀、濒危保护植物名录》的中药材加工
	氨基酸类：发酵法生产色氨酸、组氨酸、饲料用蛋氨酸等生产		
	新型抗癌药物、新型心脑血管药及新型神经系统用药生产	安乃近、扑热息痛、维生素B1、维生素B2、维生素C、维生素E、多种维生素制剂和口服钙剂生产	
	采用生物工程技术的新型药物生产		
	艾滋病疫苗、丙肝疫苗、避孕疫苗及宫颈癌、疟疾、手足口病等新型疫苗生产	纳入国家免疫规划的疫苗品种生产	
	生物疫苗生产		中药饮片的蒸、炒、灸、煅等炮制技术的应用及中成药保密处方产品的生产
	海洋药物开发与生产	麻醉药品及一类精神药品原料药生产（中方控股）	
	药品制剂：采用缓释、控释、靶向、透皮吸收等新技术的新剂型、新产品生产		

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(Continued from Page 10)

	Encouraged	Restricted	Prohibited
Pharmaceutical Industry ***(continued)***	Development and production of new excipients	Production of blood products	
	Production of crude antibacterial drugs for animals (including antibiotics and chemical synthesis API)		
	Production of new products and new formulations of antibacterial drugs, anthelmintics, insecticides, and anti-coccidiosis drugs for veterinary use		
	Production of new types of diagnostic reagents		
Medical Devices	Optical fiber bundles for image transmission, and laser optical fibers for medical treatment	N/A	N/A
	Special-function composite materials and their products (including composite-materials products for medical treatment and rehabilitation)		
	Manufacturing of electronic endoscopes		
	Manufacturing of fundus cameras		
	Manufacturing of key components of medical imaging equipment (including but not limited to high-field-strength superconducting magnetic resonance imaging equipment, X-ray-computed tomography imaging equipment, and digital color diagnostic ultrasound equipment)		
	Manufacturing of (3D) ultrasonic transducers for medical use		
	Manufacturing of equipment for boron neutron capture therapy		
	Manufacturing of image-guided, intensity-modulated radiation therapy systems		
	Manufacturing of hemodialysis machines and hemofiltration machines		
	Manufacturing of equipment for fully automated enzyme immunoassay systems (including some functions such as sample loading, enzyme labeling, plate washing, incubation, and data post-processing)		
	New technology for drug quality control and manufacturing of new equipment for drug quality control		
	Development of new analysis technology and new extracting process for active substances in natural drugs; development and manufacturing of new extracting equipment		
	Manufacturing of multi-layer, co-extrusion, water-cooled blown film equipment for non-PVC medical infusion bags		
	Development and manufacturing of large precision instruments, including electron microscopes, laser scanning microscopes, scanning tunneling microscopes, electron probes, mass spectrometers, chromatograph-mass spectrometers, nuclear magnetic resonance spectrometers, energy spectrometers, and X-ray fluorescence spectrometers		
Scientific Research and Technological Services	Bioengineering and biomedical engineering technologies and biomass energy development technology		Research and development of genetically modified organisms and production of genetically modified crop seeds, breeding livestock and poultry, and aquatic fingerlings
	Isotope, radiation, and laser technology		Development and application of human stem cell and genetic diagnosis and treatment technologies
	Marine medicine and biochemical product development technology		

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	鼓励类	限制类	禁止类
医药制造业	新型药用辅料的开发及生产	血液制品的生产	
	动物专用抗菌原料药生产（包括抗生素、化学合成类）		
	兽用抗菌药、驱虫药、杀虫药、抗球虫药新产品及新剂型生产		
	新型诊断试剂的生产		
医疗器械	传像光纤束及激光医疗光纤	不适用	不适用
	特种功能复合材料及制品（包括医用及康复用复合材料制品）		
	电子内窥镜制造		
	眼底摄影机制造		
	医用成像设备（高场强超导型磁共振成像设备、X线计算机断层成像设备、数字化彩色超声诊断设备等）关键部件的制造		
	医用超声换能器（3D）制造		
	硼中子俘获治疗设备制造		
	图像引导适型调强放射治疗系统制造		
	血液透析机、血液过滤机制造		
	全自动酶免系统（含加样、酶标、洗板、孵育、数据后处理等部分功能）设备制造		
	药品质量控制新技术、新设备制造		
	天然药物有效物质分析的新技术、提取的新工艺、新设备开发与制造		
	非PVC医用输液袋多层共挤水冷式薄膜吹塑装备制造		
	大型精密仪器开发与制造，包括电子显微镜、激光扫描显微镜、扫描隧道显微镜、电子探针、质谱仪、色谱-质谱联用仪、核磁共振波谱仪、能谱仪、X射线荧光光谱仪		
科学研究和技术服务	生物工程与生物医学工程技术、生物质能源开发技术		转基因生物研发和转基因农作物种子、种畜禽、水产苗种生产
	同位素、辐射及激光技术		人体干细胞、基因诊断与治疗技术开发和应用
	海洋医药与生化制品开发技术		

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Key Regulatory Issues

(Continued from Page 12)

registered capital of the EJV in proportion to its ownership interest. Many offshore technology owners wish to make their capital contributions in the form of technology and IP. While this is generally permitted, Chinese law and practice impose several key restrictions upon such contributions:

- First, the relevant regulations impose certain restrictions on the maximum proportion of registered capital which can be contributed in the form of non-cash assets such as IP.
- Second, while registered IP such as patents and trademarks may be contributed with relative ease, the PRC authorities will not typically acknowledge contributions in the form of unregistered IP (such as copyright or know-how). This can be problematic for partnerships in areas such as manufacturing, in which much of the IP is in unregistered form.
- Third, the PRC authorities will generally require that the IP be *assigned* to the EJV if the IP is to qualify as a capital contribution. A mere license will generally not suffice. While only the PRC rights need to be assigned, many offshore technology owners are uncomfortable with the inevitable consequential loss of control over the China IP.

For these reasons, offshore technology owners wishing to contribute technology in return for equity typically prefer to establish an offshore joint venture company that owns an onshore operating entity in China. We will examine this and other structures in more depth in the final installment in this three-part series.

Regulatory Approvals and Licenses

In addition to any categorical restrictions imposed by the Foreign Investment Catalogue, the manufacturing and sales of pharmaceuticals and medical devices are subject to a variety of licenses and approvals in China, required at various stages of a product life cycle, including product registration, manufacturing, and distribution. We discussed some of these requirements in our inaugural issue of the China Life Sciences Newsletter in 2011, and briefly review them below. Note that these licenses and approvals are required regardless of whether the FIE activity falls within the encouraged or restricted categories. Therefore, those contemplating strategic partnerships in the fields of pharmaceuticals and medical devices at the product level are well-advised to be cognizant of these licenses and approvals.

In addition to the industry-specific advertising approvals listed above, the online trading of both pharmaceuticals and medical devices will generally require an Internet Pharmaceuticals Trade Certificate and a value-added telecoms license. Most FIES will not be eligible to apply for said license. Furthermore, in order to participate in the advertising of pharmaceuticals and medical devices, a company will need to possess a business license that includes advertising business in its scope. While relatively simple to obtain for purely domestic entities, FIEs must be able to demonstrate that their direct parent companies fulfill strict experience criteria in the advertising industry in order to be eligible to apply.

Other Concerns

Technology Protection

In life science business transactions, IP is frequently the most important asset. For the IP to be valuable, it needs to adequately protect the technology and effectively exclude competitors from developing a similar technology or product. Full assessment of the value of IP requires not only a good understanding of IP law, but also deep scientific and industrial knowledge. In addition, considerations may differ significantly between China and other countries because the patentability standard is jurisdiction-dependent. For example, a patent claim directed to a medical procedure may be very strong in the U.S., yet may encounter significant patentable-subject-matter issues in China. On the other hand, a patent claim that may be deemed obvious in the U.S. may nevertheless be found sufficiently inventive in China. It is therefore important to involve IP attorneys knowledgeable about IP law both in China and offshore in the formation of any strategic partnership in China from a suitably early stage.

Dispute Resolution

It is common for IP licensors to insist that the license agreement be subject to the jurisdiction of the court of the licensor's home territory. However, the PRC has entered into relatively few bilateral enforcement treaties with other jurisdictions, and consequentially offshore judgments are unlikely to be enforceable against Chinese parties in the PRC. Conversely, as China is a party to the New York Convention, overseas arbitral awards are generally enforceable in China. As a result, offshore licensors are well-advised to include clear arbitration provisions in their license agreements.

In this issue of our China Life Sciences Newsletter, we analyzed the key regulatory and legal issues parties face when negotiating technology licenses, which can be either a standalone vehicle for R&D strategic partnerships or a key component of more complex structures. In our next issue, we will describe those more complex structures, examine how they are set up, and compare and contrast different structures and their respective advantages and shortcomings.

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1 The catalogue was initially published by the PRC Ministry of Foreign Trade and Economic Cooperation ("MOFTEC") and the State Economic and Trade Commission in 2001.

2 A VAT 'general taxpayer' has an annual turnover of more than RMB 5 million and is subject to a VAT rate of 6% in the technology transfer services. A VAT 'small-scale taxpayer' has an annual turnover of RMB 5 million or less and is subject to a VAT rate of 3% in all the pilot services.

3 Under a notice on the imposition of stamp duty on technology transfer contracts issued by the PRC State Administration of Taxation in 1989, contracts for transfer of patent application or non-patented technology are subject to a stamp duty rate of 0.03%, and contracts for transfer of patent right or patent licensing are subject to a stamp duty rate of 0.05%.

主要监管问题

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但中国法律和惯例对这类出资设置了一些重要限制：

- 首先，有关规定对以非现金资产（如知识产权）形式出资的最高比例做出了若干限制。
- 其次，尽管以注册知识产权（如专利和商标）出资相对容易，但通常中国有关机关对以非注册知识产权（如著作权或专有技术）做出的出资不予认可。这对制造领域的合作而言有些麻烦，因为该领域的多数知识产权为非注册形式。
- 最后，在知识产权可用作出资的情况下，中国有关机关通常要求将该等知识产权转让给合资公司。一般而言，仅进行许可是不够的。尽管只需转让中国的知识产权，但许多外方技术所有人对最终必然丧失对中国知识产权的控制感到不安。

因此，希望利用技术出资以获得股权的外方技术所有人通常倾向于成立一个在中国设有国内运营实体的海外合资公司。在这三部分的系列文章的最后一期中，我们会更深入地研究这个问题和其他结构。

监管批准和许可

除外资产业目录设定的任何类别上的限制外，药品及医疗器械的生产与销售在中国还需取得对产品生命周期不同阶段（包括产品注册、生产和经销）要求的各种许可和批准。我们曾在2011中国生命科学通讯创刊号中讨论过这些要求，现简要总结如下。请注意，无论外资企业活动是否属于鼓励类还是限制类，均要求获得上述许可和批准。因此，建议药品及医疗器械行业计划建立战略合作关系的企业对这些许可和批准加以了解。

除以上具体行业广告批准外，药品和医疗器械网上交易通常还需要取得互联网药品交易资格证书和增值电信业务经营许可证。多数外资企业没有资格申请该等许可证。并且，为进行制药和医疗器械广告活动，公司营业执照上的经营范围需包括广告业务。纯内资公司取得上述营业执照比较简单，而外资企业必须证明其直接母公司满足广告行业严格的经验标准后方有资格提出申请。

其它关注的问题

技术保护

在生命科学业务交易中，知识产权通常是最为重要的资产。知识产权需充分保护技术及有效防止竞争对手开发出类似的技术或产品才有价值。全面评估知识产权价值要求不仅熟知知识产权法律，还要有深厚的科学和行业知识。此外，拿中国和其他国家相比，要考虑的因素可能大不相同，因为可专利性标准因司法管辖区域而不同。例如，指向医疗程序的专利权利要求在美国可能很有效，但在中国却可能遇到严重的可专利标的物问题。从另一方面而言，在美国可能被视为缺乏创造性的专利权利要求在中国却可能被认定具有充分的创造性。因此，在中国建立任何战略合作关系时，必须尽早适时聘请熟知中国和外国知识产权法律的知识产权律师。

争议解决方式

一般知识产权许可人会坚持许可协议应受许可人所在国的法院管辖。不过，由于中国很少和其他司法管辖地签订双边执法条约，因此海外判决未必能针对中国境内的中方予以强制执行。相反，由于中国是《纽约公约》缔约国，通常可在中国强制执行海外仲裁裁决。因此，强烈建议海外许可人在其许可协议中纳入明确的仲裁条款。

在本期中国生命科学通讯中，我们分析了当事方在协商技术许可事宜时面临的重要监管和法律问题，技术许可可以是研究和开发战略合作关系的独立工具，或更为复杂的框架中的重要组成部分。在下一期通讯中，我们将介绍那些更为复杂的框架，分析它们的建立过程，对不同架构及其各自的优缺点进行比较和对比。

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1 目录最初由中华人民共和国对外经济贸易合作部（“MOFTEC”）和国家经济和贸易委员会于2001年公布。

2 年营业额超过人民币500万元的增值税‘一般纳税人’在技术转让服务中需缴纳6%的增值税。年营业额为人民币500万元或以下的增值税‘小型纳税人’在所有试点服务中需缴纳3%的营业额。

3 根据国家税务总局在1989年发出的《关于技术转让合同征收印花税的通知》，转让已申请专利的或无专利的技术的合同需缴纳0.03%的印花税，转让专利权或专利许可的合同需缴纳0.05%的印花税。

Compulsory Patent Licensing in China

By Gabriel Bloch and Gordon Milner

Recent years have seen a growing trend among developing countries such as Thailand, Malaysia, Indonesia, India, and Brazil of enacting and utilizing statutory powers to grant, or to compel a patentee to grant, patent licenses to third parties in the interests of public health.

Such powers constitute a potentially major exception to the normal near-monopoly rights and commercial discretion enjoyed by the patentee. Their exercise (or threatened exercise) has proved extremely controversial, particularly in the area of pharmaceuticals, where patentees are often looking to recoup millions of dollars invested in developing and testing the patented products.

In late 2006 and early 2007, Thailand announced public, non-commercial-use compulsory licenses for the import and local production of *efavirenz* and *lopinavir/ritonavir* (anti-HIV/AIDS drugs made by Merck and Abbott Laboratories, respectively), and an anti-clotting agent sold by Sanofi-Aventis and Bristol-Myers Squibb. More recently, on March 9, 2012, the India Patent Office issued its first compulsory license, which permitted local manufacturer Natco Pharma Ltd. to sell Bayer's patented renal oncological drug *Nexavar* in India. According to news reports, the decision was made based on the fact that Bayer was not importing the drug into India in large quantities, and that the product was priced at a level that effectively rendered it inaccessible to the local population.

China's State Intellectual Property Office ("SIPO") recently promulgated the "Measures for the Compulsory Licensing for Patent Implementation" (the "2012 Measures," issued in March of this year and effective in May). Coming within the same month as the Indian *Nexavar* decision, the publication of the 2012 Measures triggered concern in the pharmaceutical community and resulted

Pharmaceutical Licenses and Approvals

ITEMS	NAMES OF LICENSES	STATUTORY TIMELINE FOR ADMINISTRATIVE REVIEW AND APPROVAL
Registration	• Registration Certificate of Pharmaceuticals • Registration Certificate of Imported Pharmaceuticals	340 to 380 days for new pharmaceuticals following the completion of clinical trial 150 to 190 days following the completion of clinical trial
Manufacturing	• Pharmaceuticals Manufacturing License • Good Manufacturing Practices	40 working days 6 months
Distribution	• Pharmaceuticals Operation License • Good Supply Practices	45 or 60 working days 3 months
Advertising	• Pharmaceuticals Advertising Approval Number	10 working days

Medical Device Licenses and Approvals

ITEMS	NAMES OF LICENSES	STATUTORY TIMELINE FOR ADMINISTRATIVE REVIEW AND APPROVAL
Registration	• Registration Certificate of Pharmaceuticals • Registration Certificate of Imported Pharmaceuticals	Category I: 40 working days Category II: 70 working days Category III: 100 working days 90 working days
Manufacturing	• Medical Devices Manufacturing Enterprise License	40 working days
Distribution	• Medical Devices Operation License	40 working days
Advertising	• Medical Devices Advertising Approval Number	20 working days

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中国的强制性专利许可

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最近几年，在诸如泰国、马来西亚、印度尼西亚、印度和巴西这样的发展中国家，通过颁布和利用法定权力，为了公众的健康而向第三方授予或强迫专利权人向其授予专利许可证的趋势愈演愈烈。

对于专利权人所享有的正常的、近乎垄断的权利和商业自由裁量权来说，此类权力构成了一种潜在的重大例外情况。这些权力的行使（或可能的行使）证明是极具争议性的，尤其是在制药领域。在此领域中，专利权人往往都期待能够收回数以百万计美元的用于专利产品的开发和试验的投资。

2006年末和2007年初，泰国宣布对艾法韦仑和洛匹那韦/利托那韦（由默沙东公司和雅培实验室公司分别生产的抗HIV/艾滋药物）以及由赛诺菲-安万特公司和施贵宝公司销售的一种抗凝血剂的进口和本地生产授予公共非商用强制性许可。最近，在2012年3月9日，印度专利局发出了第一份强制许可，允许本地制造商 Natco制药有限公司在印度销售 德国拜耳公司受专利保护的肾肿瘤药物多吉美。新闻报道称，作出该决定的依据是拜耳公司并未向印度大量出口该药物，而且该产品的价格水平对于本地人来说是高不可及。

中国国家知识产权局最近颁布了《专利实施强制许可办法》（今年3月发布，5月生效，下称“2012年的《办法》”）。该《办法》与印度就多吉美所做的决定是同一个月内出台的，在制药界引起了关注，多家媒体纷纷以醒目标题加以报道，比如路透社称“中国修改专利法，力求获得更便宜药物”。

但是实际上，2012年的《办

制药许可和批准

项目	许可名称	行政审查和批准法定期限
注册	• 医药产品注册证 • 进口药品注册证	新药完成临床试验后340到380天 完成临床试验后150到190天
生产	• 药品生产许可证 • 药品GMP证书	40个工作日 6个月
经销	• 药品经营许可证 • 药品GSP证书	45或60个工作日 3个月
广告	• 药品广告批准文号	10 个工作日

医疗器械许可和批准

项目	许可名称	行政审查和批准法定期限
注册	• 医药产品注册证 • 进口药品注册证	一类：40个工作日 二类：70个工作日 三类：100个工作日 90个工作日
生产	• 医疗器械生产企业许可证	40个工作日
经销	• 医疗器械经营许可证	40个工作日
广告	• 医疗器械广告批准文号	20个工作日

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Patent Licensing

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in several eye-catching headlines like Reuters' "China Changes Patent Law in Fight for Cheaper Drugs."

However, in reality the 2012 Measures hardly constitute a revolution in Chinese intellectual property protection. Indeed, the basic compulsory licensing mechanism has existed in Chinese Patent Law (the "Patent Law") for well over a decade. Chapter VI of the PRC Patent Law (in its most recent 2008 incarnation) provides that a compulsory license may be awarded by SIPO when an applicant can establish one of the following circumstances:

- a patentee has failed to exploit a patent without reasonable justification for more than three years from the date of grant and four years of the date of filing;
- a patentee's patent use is determined to be monopolistic and a compulsory license would remove or reduce the anti-competitive effects of such patent use;
- public interest, extraordinary circumstances, or national emergency require a compulsory license;
- public health interests require that a compulsory license on patented medicine is granted to export the medicine to underdeveloped countries when such countries conform to the provisions of relevant international treaties; or
- major technical improvements with significant economic impact are dependent on earlier patents.

Note that compulsory licenses in the PRC are available only for invention patents and utility model patents, but not for design patents.

If the basic mechanisms have been available for some time under the Patent Law, what then has changed under the 2012 Measures?

In essence, the 2012 Measures do not significantly expand the nature of the compulsory licensing mechanisms themselves, but do clarify how the mechanisms are to be administered in the PRC from a procedural perspective. In this regard, the 2012 Measures merely constitute the next step in the evolution of and supersede the earlier, clarifying "Provisions on Compulsory Licenses," which were promulgated by SIPO in 2003, and the "Measures for Compulsory License on Patent Implementation Concerning Public Health Problems" promulgated in 2005.

In particular, the 2012 Measures:

- clarify the procedural timelines for application and response periods;
- require that the requested term for the compulsory license be specified by the applicant;
- require that the parties carry out royalty discussions and attempt to reach agreement between themselves before requesting SIPO to issue a ruling on the amount of royalty;
- clarify the circumstances under which a compulsory license may be terminated;
- clarify that a person demanding a compulsory license under the Patent Law based on alleged monopolistic practices has made reasonable requests to the patentee to obtain a license but was not successful in obtaining a license; and
- bring the compulsory licensing of medicines for public health interests into line with TRIPS requirements.

Compared to the 2005 Measures, the 2012 Measures include more detailed requirements on the export of compulsory licensed medicine: for example, that the quantity of medicine manufactured should not exceed the quantity required by the importer; that all medicine should be affixed with special labels or carry clear instructions; and that when it is feasible and will not significantly affect the price of the medicine, the medicine should be produced in special colors or shapes, or packaged using specially designed packaging.

Notwithstanding these clarifications, the 2012 Measures inherit some of the ambiguities from prior law, perhaps most significant among them a relative lack of clarity as to which factors SIPO would consider in granting a compulsory license, or how SIPO would determine royalty rates.

If the 2012 Measures do not substantially change the existing law and given that SIPO has not issued a single compulsory license in the decade that the basic underlying mechanisms have existed on the PRC statute books, should pharmaceutical companies be concerned about the publication of the 2012 Measures?

Arguably, the answer is yes—when seen in content of the wider picture. Healthcare reform forms a major pillar of the Chinese government's 12th Five-Year Economic Development Plan (2011-2015). High pharmaceutical costs coupled with a vast population are seen as a major hurdle in achieving this goal. Moreover, Chinese officials have been increasingly active high-profile participants in UN-sponsored drug access workshops such as those held last month in Bangkok, at which compulsory licensing was a key topic of discussion.

Thus, while the 2012 Measures do not substantially change the existing law, their publication may signify an increasing willingness on the part of the PRC government to use the compulsory licensing tools at its disposal either to compel a license, or perhaps as a bargaining chip to extract concessions from pharmaceutical companies and other patent holders in limited, strategically important cases. That said, competing priorities such as the desire to build and protect its own nascent biotech industry will also undoubtedly temper the government's willingness to exercise these powers and it seems unlikely that the 2012 Measures will herald a flood of compulsory licenses in China.

专利许可

(续第17页)

法》难以成为中国知识产权保护方面的一次革命。强制许可机制的确在中国《专利法》中已存在了十多年时间。中国《专利法》（最近的2008版）第六章规定，如果请求人能够证明以下情况的任何一项，国家知识产权局就可以授予强制许可：

- 专利权人自专利权被授予之日起满三年，且自提出专利申请之日起满四年，无正当理由未实施其专利；
- 专利权人行使专利权的行为被依法认定为垄断行为，而强制许可将会消除或减少该行为对竞争产生的不利影响；
- 公共利益、特殊情况、国家紧急状态要求发出强制许可；
- 公共健康利益要求对取得专利权的药品授予强制许可，以便将其出口到符合有关国际条约规定的欠发达国家；或者
- 有显著经济意义的重大技术进步是有赖于以前的专利。

应注意，中国实行的强制许可仅适用于发明专利和实用新型专利，不适用于外观设计专利。

在《专利法》规定的基本机制已经存在了一段时间的情况下，那么2012年的《办法》又带来了哪些变化呢？

本质上，2012年的《办法》并没有显著扩展强制许可机制本身的性质，但的确从程序角度说明了在中国如何对这些机制进行管理。在这方面，2012年的《办法》仅仅是对国家知识产权局于2003年颁布的《专利实施强制许可办法》和2005年颁布的《涉及公共健康问题的专利实施强制许可办法》下一步发展，并取代了这些较早的办法。

尤其是，2012年的《办法》：

- 规定了申请和答复的期限；
- 要求请求人具体说明所要求的强制许可期限；
- 要求当事人在要求国际知识产权局就使用费数额作出裁决之前首先就使用费进行协商，力求达成一致；
- 说明了终止强制许可的各种具体情况；
- 说明了根据《专利法》规定就垄断行为请求给予强制许可的个人事先应当向专利权人提供了合理的要求来获得许可，但是未能获得许可；
- 使为公共健康目的发出的药品强制许可符合了《与贸易有关的知识产权协定》的规定。

与2005年的《办法》相比，2012年的《办法》包含了与强制许可药品出口相关的更加详细的要求。例如，所生产的药品数量不得超过进口方所需的数量；所有药品都应当采用特定的标签或带有明确的说明；在可行并且不会对药品价格产生显著影响的情况下，应当对药品本身采用特殊的颜色或形状，或对药品采用特殊的包装。

虽然有这些澄清，但是2012年的《办法》依然延续了以前法律的某些不明确之处，或许其中最重要的就是对于国家知识产权局在授予强制许可时会考虑哪些因素，或者会如何认定使用费率等问题，相对来说缺乏清晰度。

鉴于2012年的《办法》并未对现有法律作出实质性改变，而且在基本机制存在于中国法典中的十年间，国家知识产权局尚未发出一项强制许可，制药公司该为2012年《办法》的公布感到忧心忡忡吗?

可以说，回答是肯定的 – 如果是从更广的角度上来看问题。医疗体制改革构成了中国政府第12个经济发展五年计划（2011～2015）的一个主要支柱。居高不下的医药费用和庞大的人口被视为实现该目标的主要障碍。此外，在联合国发起的药品可及性研讨会上，中国官员正越来越多成为积极、高调的参与者，例如上个月在曼谷举行的研讨会。在此次会上，强制许可是一个主要议题。

因此，虽然2012年的《办法》并未实质性改变现有法律，但是《办法》的公布或许意味着中国政府越来越愿意自行决定使用强制许可工具来强迫发出许可，或者可能将其作为一种筹码，以期在少数具有战略重要性的个案中从制药公司和其他专利持有人那里获得让步。虽然如此，但是其他需优先考虑的因素无疑将会遏制政府行使这些权力的冲动，例如政府希望构建并保护其新兴的生物科技产业。所以，2012年的《办法》似乎不大可能预示着中国将会发生大量的强制许可。

New Developments on the "Patentable Subject Matter" Requirement of U.S. Patent Law

By Peng Chen and Kun Wang

Two recent opinions by the Supreme Court of the United States ("Supreme Court") and the Court of Appeals of the Federal Circuit ("Federal Circuit") constitute dramatic new developments to the patentable subject matter requirement of U.S. patent law. Both cases have significant impact on patent protection for biotech inventions, especially in the diagnostics field.

Prometheus

In a unanimous decision, the Supreme Court overturned the Federal Circuit's holding in *Mayo Collaborative Services v. Prometheus Labs., Inc.* (*Prometheus*) that diagnostic method claims U.S. Patent No. 6,355,623 are not patentable based on the utility requirement of the patent law under 35 U.S.C. § 101.[1]

35 U.S.C. § 101 states (emphasis added):

> 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.

The utility requirement has been interpreted to exclude laws of nature, natural phenomena or abstract ideas. In order to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words "apply it."[2]

The Prometheus invention identifies a relationship between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove either ineffective or cause harm. Claim 1, for example, states that if the levels of 6-thioguanine (6–TG) in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per $8x10^8$ red blood cells, then the administered dose is likely to produce toxic side effects.

In the Supreme Court's decision, it identified the correlation between the blood level of 6-TG and the dosage of thiopurine as a law of nature: "The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law."[3] The Supreme Court defined the question it faces as "do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?"[4]

Claim 1 recites an "administering" step, a "determining" step, and a "wherein" step. The Supreme Court determined that the "administering" step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs, and held that the "prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.'"[5] The Supreme Court regarded the "wherein" clauses as simply telling a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient.[6] In regard to the "determining" step, the Supreme Court stated that the methods for determining metabolite levels were well-known in the art.[7] The Supreme Court held the "determining" step as relating to well-understood, routine, conventional activity, and purely conventional or obvious pre-solution activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.[8]

The Supreme Court went on to analyze previous cases it had decided on the utility issue: *Diamond v. Diehr*, 450 U.S. 175 (1981) (granting claims which encompassed natural phenomena) and *Parker v. Flook*, 437 U.S. 584 (1978) (invalidating claims encompassing natural phenomena), two cases in which the Supreme Court reached opposite conclusions about the patent eligibility of processes that embodied the equivalent of natural laws.

The *Diehr* process set forth a method for molding raw, uncured rubber into various cured, molded products using a known mathematical equation, the Arrhenius equation, to determine when (depending upon the temperature inside the mold, the time the rubber had been in the mold, and the thickness of the rubber) to open the press. The Supreme Court found the overall process patent-eligible because of the way the additional steps of the process were not obvious, already in use, or purely conventional.[9] The process in *Flook* provided a method for adjusting "alarm limits" in the catalytic conversion of hydrocarbons by measuring the level of the variable, e.g., the temperature, and using a novel mathematical algorithm to calculate the alarm limits. The Supreme Court held the process unpatentable because "[t]he chemical processes involved in catalytic conversion of hydrocarbons[,] . . . the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for 'automatic monitoring-alarming'" were all "well known," to the point where, putting the formula to the side, there was no "inventive concept" in the claimed application of the formula.[10] The Supreme Court held the claims by Prometheus no stronger than the claims in *Flook*, which include instructions that add nothing specific to the laws of nature other

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关于美国《专利法》中“可专利标的物”要求的最新发展情况

作者： 陈朋，王筮

美国最高法院（“最高法院”）和联邦巡回上诉法院（“联邦上诉法院”）最近针对两起案件作出的判决意见书表明了美国专利法中可专利标的物要求的最新快速发展情况。这两起案件对生物技术发明的专利保护具有重大影响，尤其是诊断领域的技术发明。

*Prometheus*案

在意见一致的判决中，最高法院驳回了联邦上诉法院在*Mayo Collaborative Services 诉Prometheus Labs., Inc.*（*Prometheus*）案件中的判决，裁定诊断方法权利要求（美国专利号：6,355,623）根据《美国法典》第35篇第101条的实用要求不具有可专利性。[1]

《美国法典》第35篇第101条规定（着重强调）：

> 无论何人，只要其发明或发现了任何新型实用的程序、机器、生产工艺或物质成分，或对上述各项做出了新型实用的改进，并符合本法所规定之条件和要求，都有权取得相应的专利权。

实用要求的司法解释排除了自然法则、自然现象或抽象概念。为了将不可专利的自然法则转换为对该等法则的具有专利适格性的应用，申请者需要做的决不是在陈述自然法则的同时仅仅写上“加以应用”字样。[2]

Prometheus的发明确认了血液中某些代谢物的浓度与硫嘌呤类药物施药剂量或无效或造成危害可能性之间的关系。例如，权利要求1表示：如果（服用硫嘌呤类药物病人）血液中的6-硫鸟嘌呤（6–TG）水平超过每$8x10^8$个红细胞约400皮摩尔，则所施药量很可能产生毒副作用。

最高法院的判决认为血液中6–TG的水平与硫嘌呤类药物施药剂量之间的关系是自然法则：“其关系就是身体代谢硫嘌呤类药物复合物方式的后果-完全属于自然过程。因此仅描述该等关系的专利阐述的是一项自然法则。”[3] 最高法院将其面临的问题定义为“专利权利要求确实向其关系陈述中补充了足够的信息以使其描述的程序有资格成为应用自然法则的具有专利适格性的程序吗？”[4]

权利要求1详述了“施药”步骤、“确定”步骤和“其中”步骤。最高法院认为“施药”步骤仅提及了有关人员，即使用含有硫嘌呤类药物为身患某些疾病的病人进行治疗的医生，而且最高法院认为“‘试图将配方的使用限于特定的技术环境无法避免’对于抽象概念专利权的禁止。”[5]

最高法院认为“其中”条款仅是告诉了医生有关自然法则，最多也就是建议其在为其病人进行治疗时应考虑这一自然法则。[6]

就“确定”步骤而言，最高法院称确定代谢物水平的方法在业界是广为人知的。[7] 最高法院认为“确定”步骤与已知的、常规的、常见的行为有关，而且完全常见的或显而易见的解决前行为通常不足以将不可专利的自然法则转换为对该等法则的具有专利适格性的应用。[8]

最高法院继续分析了先前其针对实用问题作出判决的案件：*Diamond 诉Diehr*，450 U.S. 175（1981）（同意包含自然现象的权利要求）以及*Parker诉Flook*，437 U.S. 584（1978）（认为包含自然现象的权利要求无效）。在这两起案件中，高等法院对包含了同样自然法则的程序的专利适格性作出了相反的判决。

*Diehr*的程序阐述了一种将未经处理的、未经熟化的橡胶加工为各种熟化的、成型的产品，该程序使用已知的数学方程式、Arrhenius方程式确定打开模具的时间（根据模具内的温度、橡胶在模具内的时间以及橡胶厚度决定）。最高法院判定整个程序具有专利适格性，因为程序额外步骤的方法并不是显而易见的，并不是已经使用的或者完全是常见的。[9] *Flook*的程序提供了一种修正碳氢化合物催化转化装置中“报警值”的方法，该报警值是通过测量可变参数（如：温度）的水平，使用新数学算法计算报警值的方式确定的。最高法院判定该程序不具有可专利性，因为“碳氢化合物催化转化中涉及的化学程序[,]．．．监控化学程序可变参数的做法、使用报警值促发报警、报警值必须重新计算和重新调整的概念以及使用计算机自动监控报警”是“已知的，”就此而言，抛开公式不说，所主张的公式应用不

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U.S. Patent Law

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than what is well-understood, routine, conventional activity, previously engaged in by those in the field.[11]

The Supreme Court further justified its holding by adding policy concerns that "there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to 'apply the natural law,' or otherwise forecloses more future invention than the underlying discovery could reasonably justify."[12] The Supreme Court was troubled by the claims because the patent claims do not confine their reach to particular applications of the natural law, unlike a typical patent on a new drug or a new way of using an existing drug.[13]

Myriad

In *Association for Molecular Pathology v. USPTO and Myriad Genetics* (*Myriad*), the Federal Circuit held that the challenged composition claims covering two "isolated" human genes, *BRCA1* and *BRCA2*, are drawn to patentable subject matter because the claims cover molecules that are markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature.[14]

In its analysis, the Federal Circuit took the position that Myriad's claimed isolated DNAs exist in a distinctive chemical form—as distinctive chemical molecules—from DNAs in the human body, i.e., native DNA. After a lengthy discussion of the basics of molecular biology, the Federal Circuit distinguished native DNA from isolated DNA because native DNA exists in the body as a large, contiguous DNA molecule which is an integral part of a larger structural complex, i.e., a chromosome, whereas isolated DNA is a freestanding portion of a native DNA molecule, frequently a single gene.[15] Accordingly, human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA. The Federal Circuit rejected the approach taken by the district court, which looks not at whether isolated DNAs are markedly different—have a distinctive characteristic—from naturally occurring DNAs, as the Supreme Court has directed, but at one similarity: the information content contained in isolated and native DNAs' nucleotide sequence.[16]

All but one of the challenged method claims cover methods of "analyzing" or "comparing" a patient's *BRCA* sequence with the normal, or wild-type, sequence to identify the presence of cancer-predisposing mutations. The Federal Circuit concluded that Myriad's claims to "comparing" or "analyzing" two gene sequences fall outside the scope of § 101 because they claim only abstract mental processes.[17] Limiting the comparison to just the *BRCA* genes or just the identification of particular alterations fails to render the claimed process patent-eligible, because "the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of the formula to a particular technological environment."[18] The Federal Circuit further noted Myriad's challenged method claims are distinguishable from the claims upheld under § 101 in its earlier decision[19] (overturned by the Supreme Court in *Prometheus* as discussed above). In holding that the claims in *Prometheus* satisfied § 101, the Federal Circuit concluded that, in addition to the "administering" step being transformative, the "determining" step was both transformative and central to the purpose of the claims. Specifically, the court held that because the metabolite levels could not be determined by mere inspection, the determining step necessarily required a transformation.[20]

In regard to Myriad's method claim directed to a method for screening potential cancer therapeutics via changes in cell growth rates, the Federal Circuit concluded that the claim includes transformative steps, an "important clue" that it is drawn to a patent-eligible process.[21] The Federal Circuit pointed out that the claim recites a method that comprises the steps of (1) "growing" host cells transformed with an altered *BRCA1* gene in the presence or absence of a potential cancer therapeutic, (2) "determining" the growth rate of the host cells with or without the potential therapeutic, and (3) "comparing" the growth rate of the host cells. Therefore, the claim was determined to include more than the abstract mental step of looking at two numbers and "comparing" two host cells' growth rates.

Following its decision in *Prometheus*, the Supreme Court on March 26, 2012 vacated the Federal Circuit's holding in *Myriad* and ordered the Federal Circuit to reconsider its holding in light of *Prometheus*.

According to some commentators, the Federal Circuit could logically find that the information in the DNA represents a law of nature, that the DNA itself is a natural phenomenon, that the isolation of the DNA simply employs an isolation process already well-known and expected at the time of the invention, and ultimately that the isolated DNA is unpatentable because it effectively claims a law of nature or natural phenomenon.[22] However, one distinguishing point is that *Prometheus* claimed a process while *Myriad* claims a composition of matter. For example, in a June 15, 2012 amicus brief, the American Intellectual Property Law Association (AIPLA) argued to the Federal Circuit that the Supreme Court's decision in *Prometheus* does not require the appellate court to change its decision in *Myriad*. The AIPLA argued that the rationale applied in *Prometheus* to

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美国《专利法》

(续第21页)

具有“创新理念”。[10] 最高法院认为Prometheus的权利要求并不比*Flook*案件中的权利要求更强。除了之前业内人士进行的已被知的、常规的、常见的活动外，Prometheus的权利要求包括的指示中并未在自然法则上添加任何其他特殊内容。[11]

最高法院通过补充下述政策考量进一步证明其判决：“授予与其使用捆绑在一起的专利会抑制未来基于该等专利进行创新，这是可能存在的一种风险。当一项获得专利的程序意味着仅仅是对‘适用自然法则的’说明，或者与可以被合理确定的有关发现相比会以其他方式阻止未来更多发明时，这种风险就变得更严重。”[12] 最高法院对权利要求表示困扰，因为与关于新药物或使用现有药物新方法的典型专利不同，专利权利要求并未限定其对自然法则的特殊应用。[13]

*Myriad*案

在*美国分子病理协会诉美国专利商标局及Myriad Genetics*（*Myriad*）案中，联邦上诉法院裁定受到质疑的组合权利要求包含两种“分离的”人类基因片段*BRCA1*和*BRCA2*，其被列为可专利标的物，因为该等权利要求包含的分子与自然界存在的分子显著不同—拥有独特的化学特性和性质。[14]

联邦上诉法院在其分析中认为Myriad主张的分离脱氧核糖核酸（DNA）以独特的化学形式—作为独特的化学分子—存在，其与人体内的DNA即自然DNA不同。在对分子生物学的基本原理进行漫长的讨论后，联邦上诉法院认为自然DNA有别于分离的DNA，因为自然DNA作为一个大的、连续的DNA分子存在于人体内，其为更大的结构复合体（即染色体）的不可或缺的组成部分；而分离的DNA是自然DNA分子的独立的部分，常称为单基因。[15] 因此，分离或合成部分自然染色体DNA的人为干预赋予了分离的DNA不同于自然DNA特性的独特的化学特性。联邦上诉法院驳回了地方法院采用的方法，该方法评判的不是分离的DNA是否与自然产生的DNA显著不同，即是否具有独特的特征，如最高法院所指示，而是着重于二者之间的相似点：分离的DNA与自然DNA的核苷酸序列包含的信息内容。[16]

除其中一项以外，所有受到质疑的方法权利要求都包含为确定是否存在促使癌症发生的突变而对病人的*BRCA*序列进行“分析”或将病人的*BRCA*序列与正常序列或野生型序列进行“比较”的方法。联邦上诉法院认定Myriad的“比较”或“分析”两种基因序列的权利要求不在第101条规定的范围之内，因为他们仅就抽象的心理过程提出权利要求。[17] 将比较仅限于*BRCA*基因或对特定变化的确定无法使其主张的方法具有专利适格性，因为“试图将配方的使用限于特定的技术环境无法避免禁止授予抽象概念专利权”。[18] 联邦上诉法院还指出Myriad受到质疑的方法权利要求与其在其先前判决[19]（如上所述，在*Prometheus*案中被最高法院推翻）中根据第101条支持的权利要求有所不同。在判定*Prometheus*案中的权利要求符合第101条的规定时，联邦上诉法院认为，除了“施药”步骤属于有转换性的，“确定”步骤对于权利要求的目的而言不仅具有转换性而且属于核心内容。确切地说，法院认为由于代谢物水平不能单纯由检验确定，因此确定步骤必然要求进行转换。[20]

对于Myriad与通过细胞生长速率变化筛查潜在癌症疗法的方法有关的方法权利要求，联邦上诉法院认为该权利要求包括转换步骤，这是可将其归类为具有专利适格性的方法的“重要线索”。[21] 联邦上诉法院指出该权利要求列举了包括以下三项步骤的方法：（1）在存在或不存在潜在癌症疗法时“培养”随*BRCA1*基因的改变而进行转换的宿主细胞，（2）“确定”宿主细胞在存在或不存在潜在疗法时的生长速率，（3）“比较”宿主细胞的生长速率。因此，权利要求被裁定为不仅仅包括评判两项数字和“比较”两项宿主生长速率的抽象心理步骤。

继其就*Prometheus*案做出的判决后，最高法院于2012年3月16日取消了联邦上诉法院在*Myriad*案中做出的裁定，并命令联邦上诉法院根据*Prometheus*案重新审议其裁定。

根据某些评论员的观点，逻辑上联邦上诉法院可裁定（1）DNA中的信息体现了一种自然法则，（2）DNA本身是一种自然现象，（3）分离DNA仅采用

(第25页继续)

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process claims does not apply to Myriad's isolated DNA inventions.

Impact of the *Prometheus* and *Myriad* Decisions

The holdings by the Supreme Court in *Prometheus* and the Federal Circuit in *Myriad* present heightened level of scrutiny on method claims based on the patentable subject matter requirement. In both cases, claims directed to diagnostic methods including "measuring" or "comparing" steps were invalidated. Following *Prometheus* and *Myriad*, method claims reciting routine "administering" or "determining" steps might not be enough to satisfy the patentable subject matter requirement because they can be viewed as "conventional or obvious" pre-solution or post-solution activities which are not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.

The U.S. Patent and Trademark Office (USPTO) on July 3, 2012 issued a memorandum providing more guidance for the biotechnology industry on how to apply the U.S. Supreme Court's *Prometheus* ruling. According to the memo, the key question that examiners must consider is whether the claimed invention includes additional steps that ensure the claim amounts to "significantly more" than the natural phenomenon itself. "If no, the claim is not patent-eligible and should be rejected," the USPTO said. If the patent does cover a law of nature, the examiner should consider whether it includes elements that ensure the claim amounts to significantly more than the natural principle itself. "The analysis turns on whether the claim has added enough to show a practical application," the memo states.

The heightened level of scrutiny on method claims by the courts and the new guidelines by the USPTO may hold back innovations in the diagnostics and personalized medicine fields by stoking more litigation and confusing biotechnology companies about what they can patent. Depending on the final outcome of the *Myriad* case, biotech companies could lose more protection to their intellectual property in the form of gene patents, and thus have less incentive to publish their inventions by filing patent applications, but rather be more inclined to seek protection in the form of trade secrets.

Implications of the recent developments in U.S. patent law for the Chinese life sciences industry could be two-fold. On the one hand, this could mean diagnostics service providers in the U.S. will have less incentive to outsource to Chinese companies in order to circumvent patent protections in the U.S. On the other hand, the reduced patent protection for biotech discoveries in the U.S. could represent a golden opportunity for the Chinese life sciences industry to enter the U.S. market, which has been less accessible to Chinese companies in the past. Chinese companies in the diagnostics and personalized medicine fields, in particular, may consider realigning their global strategies with the changed patent landscape in the U.S., and add the U.S. as a target market in the near future.

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1 566 U.S. ____ (2012).

2 *Id.* at *3.

3 *Id.* at *8.

4 *Id.* (emphasis in original).

5 *Id.* at *9 (quoting *Bilski v. Kappos*, 130 S.Ct. 3218, 3230 (2010)).

6 *Id.* at *9-10.

7 *Id.* at *10.

8 *Id.*

9 *Diehr*, 450 U.S. at 187.

10 *Flook*, 437 U.S., at 594.

11 *Prometheus*, 566 U.S. at *13.

12 *Id.* at *17.

13 *Id.* at *18.

14 653 F.3d 1329 (Fed. Cir. 2011).

15 *Id.* at *41-42.

16 *Id.* at *18.

17 *Id.* at *44-45.

18 *Id.* at *49-50.

19 *Id.* at *50 (quoting *Bilski*, 130 S.Ct. at 3230).

20 *Id.* at *52.

21 *Id.* at *53.

22 www.PatentlyO.com.

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了在发明之时已为人所知并可预期的一种分离方法，以及（4）分离的DNA不可专利，因为其实际上主张的是自然法则或自然现象。[22] 不过，不同的是*Prometheus*主张的是一种方法，而*Myriad*主张的是物的组合。例如，2012年6月15日的一份法庭简报中，美国知识产权法学会（知识产权法学会）向联邦上诉法院提出意见，表示最高法院在*Prometheus*案中做出的判决并未要求上诉法院改变其在*Myriad*案中做出的判决。知识产权法学会认为*Prometheus*案中用于方法权利要求的基本原理不适用于*Myriad*的分离的DNA发明。

*Prometheus*案及*Myriad*案判决带来的影响

最高法院在*Prometheus*案中做出的裁决提高了根据可专利标的物要求对方法权利要求的审查标准。两起案件中的含有“测量”或“比较”步骤的诊断方法权利要求被判定无效。继*Prometheus*案和*Myriad*案后，列有常规的“施药”或“确定”步骤的方法权利要求可能不足以满足可专利标的物要求，因为该等步骤可被视为“常见的或显而易见的”解决前或解决后活动，其不足以将不可专利的自然法则转换为对该等法则的具有专利适格性的应用。

2012年7月3日，美国专利商标局（专利商标局）发布了一份备忘录，为生物技术行业如何应用美国最高法院就*Prometheus*案做出的裁决提供了更多的指引。根据备忘录，审查员必须考虑的关键问题是所主张的发明是否含有能确保权利要求“远远超出”自然现象本身的其他步骤。“如果不含该等步骤，则权利要求不具专利适格性，应予以驳回”，专利商标局如是说。如专利确实包含自然法则，审查员应考虑其是否包含能确保权利要求“远远超出”自然原理本身的原理。备忘录表示“分析取决于权利要求是否包括足够的内容来证明实际应用性”。

经法院提高的对方法权利要求的审查标准及专利商标局发布的新的指引可能会引发更多的诉讼并使生物技术公司对什么才是可专利标的物感到困惑，从而阻碍诊断和个性化医疗领域的创新。根据*Myriad*案的最终结果，生物技术公司可能会丧失对其基因专利知识产权的更多保护，并因此不再有那么大的动力通过提交专利申请公布其发明，而更倾向于以商业秘密的形式寻求保护。

美国专利法的最新进展带来的影响对中国生命科学行业来说是把双刃剑。一方面，这意味着美国的诊断服务提供商将不再有那么大的动力为了规避在美国进行专利保护而向中国公司进行外包，另一方面，在美国对生物技术发明的专利保护的减少对中国生命科学行业进入美国市场而言则是一次绝好的机会，因为在过去中国公司进入美国市场并不那么容易。特别是，诊断和个性化医疗领域的中国公司可考虑将其全球战略与美国发生变化的专利形势相结合，并在不久的将来将美国作为目标市场。

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1 566 U.S. ____ (2012)。
2. *同上*第*3页。
3. *同上*第*8页。
4. *同上*（原文强调）。
5. *同上*第*9页（引用*Bilski*对*Kappos*案，130 S.Ct. 3218, 3230（2010））。
6. *同上*第*9-10页。
7. *同上*第*10页。
8. *同上*。
9. *Diehr*，450 U.S.第187页。
10. *Flook*，437 U.S. 第594页。
11. *Prometheus*，566 U.S. 第13页。
12. *同上*第*17页。
13. *同上*第*18页。
14. 《联邦判例汇编》第三辑第653卷第1329页（联邦巡回上诉法院2011年）。
15. *同上*第*41-42页。
16. *同上*第*44-45页。
17. *同上*第*49-50页。
18. *同上*第*50页（引用*Bilski*案，《最高法院案例汇编》第130卷第3230页）。
19. *同上*第*52页。
20. *同上*。
21. *同上*第*53页。
22. www.PatentlyO.com 。

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