China Life Sciences 中国生命科学通讯 Newsletter

Welcome to the Spring 2012 issue of our *China Life Sciences Newsletter*. In our second edition, we remain focused on sharing insights from key players in the China life science ecosystem, identifying trends and best practices in China life science transactions, and keeping our clients and friends apprised of the latest regulatory developments affecting the industry.

The first article in this issue includes a thought-provoking interview with John Oyler, the CEO and founder of BeiGene, a fast-growing China-based biotech firm focused on oncology drug discovery to meet the needs of cancer patients in China and the greater Asia-Pacific region. Among other things, Mr. Oyler shares his outlook on the evolution of various segments of the industry, fundraising and cross-border partnering, the impact of PRC health care regulation and reform, and China-based research teams. The next article is the first in a two-part series discussing the strategic partnerships between Western and Chinese companies for the purpose of conducting early-stage pharma and biotech R&D. In this issue, we highlight the dynamics of these strategic partnerships between Western and Chinese companies, and offer some practical guidance on how to best plan for such partnerships. In the next segment, we will provide more detailed guidance and best practices on how to best execute such transactions. The third and final article in this issue offers a detailed examination of the USPTO's proposed regulations on preissuance submissions of patent applications.

As always, we welcome your ideas and feedback—please email the editors, Chuck Comey, Thomas Chou, or Peng Chen with any requests or suggestions for future issues.

In This Issue

目录

欢迎阅读本所2012年春季《中国生命科学通讯》。在第二期，我们的重点仍然是分享中国生命科学生态系统内主要参与者的看法，确定中国生命科学交易领域的各种趋势及最佳做法，并使我们的客户和朋友了解影响该行业的最新法规动态。

本期的第一篇文章包括对百济神州科技有限公司首席执行官兼创始人欧伊乐（John Oyler）进行的发人深省的访谈。百济神州是中国一家快速成长的生物科技公司，其业务重点是研发抗肿瘤药物，以满足中国和大亚太区肿瘤患者的需求。欧先生谈了他对该行业各领域发展状况、融资和跨境合作、中国保健法规和改革的影响以及中国研究团队等问题的看法。第二篇文章分两部分，本期刊登的是第一部分。本部分讨论了中国和西方公司为进行药物和生物技术前期研发进行的战略合作事宜。在本期，我们重点讨论了中国和西方公司进行此类战略合作的动态，并就如何对此类合作做出最佳规划提供了一些实用指引。在下一部分，我们将就如何以最佳方式执行此类交易提供更为详细的指引和最佳做法。本期的第三篇和最后一篇文章详细分析了美国专利商标局针对专利申请中的专利颁发前呈报事宜提议制定的法规。

像以往一样，我们欢迎您发表意见、做出反馈。如对以后发表的通讯有任何要求或建议，请发电邮与下列编辑联系：柯弥律师、周至恒律师或陈朋律师。

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Investor Q&A

Profile: John V. Oyler, Founder & CEO, BeiGene Ltd.

Interview by Chuck Comey, Dave Chang, and Patrick Fischer

John Oyler is the founder and CEO of BeiGene Ltd., a Beijing-based biotechnology company that focuses on discovering and developing innovative oncology drugs. Few can match Mr. Oyler's record as a serial founder. He previously founded and was CEO of BioDuro, a 700-person integrated contract research organization (CRO) in Beijing, which was sold to PPD with attractive returns. Mr. Oyler is also the former CEO of Galenea, a Boston-based biotech spinout from Massachusetts Institute of Technology with funding from Otsuka; the former co-CEO of Genta, a publicly traded oncology company that grew to be worth $1.7 billion; and the former founder and president of Telephia, which was bought by Nielsen. He holds an MBA from Stanford University and a BS from Massachusetts Institute of Technology.

Q: How do you feel about the market in 2012 for emerging companies in the biotech and life sciences industry globally? In China? What do you see as the key trends and drivers this year?

A: I have a pretty positive view of the market for emerging companies in the biotech and life sciences industry at the moment. These sectors have had a nicer last six months than we've seen in awhile. You can look at the recent IPOs of companies like Clovis, and they're not the only example. The ability of such companies to become liquid is a positive sign for others.

From a China perspective, we're seeing lots of interest and momentum. People who are present in this space are seeing the potential for value creation in biotech from core businesses, not just CROs.

In terms of key trends and drivers for 2012, today for the first time there are very good, high-quality assets that pharmaceutical companies are licensing to biotech companies that jump in and provide risk capital and a talented team, and move the assets forward in a way that creates economic returns that investors are very interested in. Clovis is a great example of that. Hopefully BeiGene will be an example, too.

Also, there's beginning to be an understanding of the value of being first in China. China has a fifth of the world's population, and even if you're a fast follower who might be third in class or fourth in class, you have the ability to be first in class in China. And a lot of the drugs that are first in class are not on a clinical path here in China, so you can actually beat them to market. A great example is Hutchison, who recently did a deal with AstraZeneca where AstraZeneca paid $20 million up-front for a c-MET inhibitor. Right now c-MET inhibitors globally wouldn't get a million dollars up front. But in China, if you're first in China, there is a huge premium.

Q: Foreign companies have long been partnering with Chinese scientific talent to help drive their R&D efforts, yet Chinese companies themselves have not historically been known for being innovators when it comes to drug development. Do you sense a shift now happening, as Chinese companies strive to innovate and develop their own drugs?

A: Chinese companies are certainly striving to be world-class innovators in drug development and will inevitably succeed, but it will take time. The vast majority of partnering to date has been fee-for-service CRO work. Ten years ago, people questioned whether you could even do that in China, but now it's a very real and common practice and we're seeing unexpectedly good-quality work. People may not be aware, but today there is robust innovation in the fast-follower space in China, which shows creativity and innovation from a medicinal chemistry or drug development perspective. But cutting-edge, world-class biology that will help define the next class of targets is only being done in China today at the academic level and within very few companies, and it will take some time for China to build that expertise and capability more broadly.

Q: How does China's biotech and life sciences industry, in particular with regard to drug development, currently compare to the rest of the world? China has historically been seen as a producer of generic drugs, but not as a leader in pharma biotech. Do you see this changing? How long before we can expect to see a "Genentech of China" emerge and produce best-in-class drugs?

A: Compared to the rest of the world, China has a fundamentally strong technical expertise in a broad range of areas necessary to drug discovery. There are gaps, for example, with respect to international standards of best laboratory practice, but there are teams in China that are putting such standards in place, and I think that these gaps will be filled in the next five years or so.

In terms of innovation, you don't expect every company in China to be the most innovative company in the world. You don't expect every company in China to be world-class in biology. But inevitably, you can easily see a dozen really good companies that have great teams that push forward, and some of those will be successful and will turn into China's Genentech. Right now there are a few such companies in place, and over the next five years I expect there will be far more than a dozen in place, which should set the tone for a very successful and very robust, innovative, and novel drug capability in China, just like anywhere else in the world.

Q: What are the key differences between developing drugs in China and in the U.S, especially based on your past experience at Genta? What are the advantages and disadvantages of basing BeiGene in China?

A: From a research and a team quality perspective, I see no difference at all. BeiGene is a leading company and one of

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人物简介

人物简介：百济神州有限公司创始人兼首席执行官欧伊乐（John V. Oyler）

柯弥、张德先和Patrick Fischer与欧伊乐访谈录

欧伊乐是百济神州生物科技有限公司的创始人兼首席执行官。百济神州是一家位于北京的生物技术公司，主要从事创新型抗肿瘤药物的发现与开发。欧先生担任过很多公司的创始人，在这点上很少有人能比得上他。欧先生先前创立了保诺（BioDuro）公司，并担任该公司的首席执行官。保诺公司是北京一家拥有700人的综合研发承包机构（CRO），其被以可观的价格出售给了PPD公司。欧先生还是Galenea公司的创始人。Galenea位于波士顿，是一家从麻省理工学院剥离出来的生物技术公司，公司得到了大冢公司提供的资金支持。欧先生曾是Genta的前联合首席执行官。Genta是一家上市的抗肿瘤公司，其价值已经达到了17亿美元。欧先生还是被Nielsen收购的Telephia公司的前创始人和总裁。他获得了斯坦福大学工商管理硕士学位，并从麻省理工学院取得学士学位。

问：您认为2012年全球生物技术和生命科学行业中新兴公司的市场情况如何？中国的情况呢？您认为今年的主要趋势和驱动力是什么？

答：目前我非常看好生物技术和生命科学行业中新兴公司的市场。这些行业在过去半年的情况要比我们近期看到的要好。你可以看到最近像Clovis这样的公司在进行上市，而它们并不是个例。这些公司能在市场流通对其它公司来说是一个积极的信号。

从中国的情况来说，我们正看到很多的兴趣和势头。在这个领域中的人也看到在生物技术行业从核心业务而不仅仅是从合同研究组织中创造价值的潜力。

从2012年的主要趋势和驱动力方面而言，现在制药公司第一次把非常好的优质资产许可给生物技术公司，由后者提供风险资本和人才团队，并推动资产使其创造投资人都很感兴趣的经济回报。Clovis就是这方面的一个很好例子。希望百济神州也将成为一个这样的例子。

此外，在中国成为开拓者的价值开始被理解了。中国拥有世界五分之一的人口，即使你可能只是一个三流或者四流的快速跟随者，你也有能力在中国成为同类第一。有很多一流的药物还没有在中国应用到临床，因此你实际上可以占领市场。和记黄埔就是一个很好的例子，该公司最近与AstraZeneca公司达成了一笔交易，由AstraZeneca公司为一种c-MET抑制剂支付2000万美元的前期资金。现在全球范围内c-MET抑制剂连100万美元预付款也得不到。但是在中国，如果你是中国第一，就会有巨大的溢价。

问：外国公司长久以来一直与中国科学界的精英合作帮助推动其研发工作，然而就药物开发而言，一直以来中国公司本身并未作为创新者而闻名。随着中国公司自身努力进行创新并开发其自己的药物，您感觉到现在的情况正在发生改变吗？

答：中国的公司当然在努力成为世界级的药物开发创新者并且肯定会成功，但这需要时间。目前绝大多数的伙伴关系都还是按服务收费的CRO工作。十年前，对中国能否做到这一点人们都表示怀疑，但是现在这是非常真实普遍的活动而且我们看到这项工作的质量好得出乎意料。人们可能没有意识到，但是作为一个快步追赶的追随者，如今的中国有着极大的创新能力，从医药化学或药物开发视角来看，这显示了中国的创造力和创新能力。但是先进的、世界级的、将会有助于界定下一类目标的生物学今天在中国还仅仅停留在学术层面和为数极少的公司，中国要更加广泛地建立起这方面的专业知识和能力还需要一些时间。

问：与世界其他地方相比，中国生物技术和生命科学行业（尤其是就药品开发而言）的现状如何？中国一直被视为仿制药的生产者，而不是制药生物技术的领先者。您觉得这种情况在改变吗？我们还需要等多久才能看到“中国的基因泰克”兴起并生产同类最佳药物？仿制药

答：与世界其它地方相比，中国在广泛的领域具有基础雄厚的对药物发现所必需的专业技术。差距是有的，比如在最佳实验室实践的国际标准方面，但是中国有些团队正在把此类标准付诸实施，我想再过五年左右的时间，这些差距就会被填补。

就创新而言，别指望中国的每个公司都是世界最有创新能力的公司。也别指望中国的每个公司都是生物学领域的世界级公司。但是可以肯定的是，你可以很容易地看到一二十家真正优秀的、拥有精良团队的公司在向前推进，其中有一些会取得成功，成为中国版本的基因泰克公司。目前，已经有几个这样的公司，在下个五年里，我预计这类公司的数量将远远超过一二十家，像世界其他地方一样，它们应该为中国非常成功的、非常强大的新药物创新能力奠定基调。

问：根据您以往在Genta的经验，您觉得在中国和美国进行药物开发的主要区别是什么？把百济神州总部设在中国的优势和劣势是什么？

答：从研究和团队素质的角度来说，我看不到任何不同。百济神州是一个领先的公司，也是中国最佳

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Q&A

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the best places to work in China, and I think that the caliber of team that we can recruit here is as good as any team that we could recruit anywhere else in the world.

From a development perspective, it is different because the regulatory system in China is very different. The approval period is longer, and it is not a level playing field. Local companies are treated differently than foreign companies. Leading local companies can have their projects prioritized, which can help expedite them through the system. If you are interested in doing drug discovery in China, it's much better to be a leading local company because you are at an advantage. So our approach at BeiGene has been to build an organization that is a local company and that fits exactly with what China wants to do. That's what we think the right approach is within the current Chinese regulatory system.

Another difference is that there are enough people in China that your patient accumulation for trials is very quick, and the costs are a fraction of what they would be in the United States or in Europe. Finally, there is a focus by the SFDA (China's FDA) on safety. The safety hurdles associated with running clinical trials in China is probably higher than it is in other countries.

Q: Is the current regulatory environment in China helping or hindering drug development by companies such as BeiGene?

A: The current regulatory environment in China is hindering the industry as a whole. It is not malicious, and there is a logical reason behind it. Right now, the SFDA doesn't have the capabilities to widely open up the doors and provide an even playing field to everyone. There are simply not enough reviewers. As a result, they're only going to let a few people through, and from their perspective those few people should be the leading local companies. And we believe that as a local company in China focusing on important projects, we can use the current regulatory system to our advantage by having our projects prioritized. But I do think that it is very important for the industry as a whole that the SFDA expands its review capabilities and continues to evolve as an organization, thus leveling the playing field. And the SFDA is evolving. Like everything else in China, it is very different today than it was five years ago and I expect it will be very different five years from now.

Q: BeiGene signed co-development and license deals with Janssen Pharmaceuticals last year. What advice do you have for U.S. biotech companies seeking to partner with local Chinese companies to co-develop drugs? What advice do you have for Chinese companies looking to partner with U.S. biotech companies? What are common pitfalls to avoid in co-development arrangements between U.S. and Chinese drug research companies?

A: For U.S. biotech companies seeking to partner with local Chinese companies to co-develop drugs, my main advice is that you always have to be careful who you partner with, focusing on your partner's quality and culture and ensuring that you have aligned interests and economics. This advice applies to a project anywhere, but when you are partnering with someone who is halfway around the world, and it is a cross-cultural partnership, there is a lot of room for misunderstanding and misinterpretation. You have to be careful about your partner's reputation. Most people in China will know who your partner is, and your partner will carry a reputation that can be good or bad, honest or dishonest, high quality or not. And every time you sit down with someone else in China, you bring your partner to the table with you.

For Chinese companies looking to partner with U.S. biotech companies, my advice is to put in place a team that the U.S. company will respect and trust, which means that you have to recruit the right people and compensate them in a way that makes you attractive. I think that a lot of times that's a hard thing for Chinese companies to do and understand. It's a big investment. But it's necessary, frankly, if you want to partner with U.S. companies.

Q: What is the outlook for China-based drug development companies in terms of raising money, such as financings from venture capital funds? What expectations should investors and founders have at this point for acquisition exits or IPOs?

A: For a China-based drug development company to raise money from Western venture capital firms, you need to put in place a team that Western firms respect and that makes them feel comfortable. A Chinese company that doesn't have the right team will not be able to access capital from the Western markets. But there are all sorts of different funds that are being set up here in China. I do think that you'll see lots of people that the Western world wouldn't fund being funded in China instead. Chinese funds know them, understand them, and trust them.

And I think that the outlook is good. You've already seen good signs in China in companies such as Hutchison and Beta Pharma. And if you look back at the investments that were made over the last 10 years, which were predominantly in the CRO space, I think that if you had put $1,000 in every company that was funded by a legitimate VC funded by offshore money, your return would certainly be in excess of three times the invested capital. And it may be closer to four or five times. That return outperforms most venture capitalists in China, whether in biotech or not. There are limited companies that are playing in the space here and so there is a big opportunity.

In terms of realistic expectations that investors and founders should have for potential mergers and acquisitions or IPOs, I think that there will be lots more IPOs by pharma companies that are selling to China and health care service providers in China. These are the industries that are growing over time.

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人物简介

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的工作场所之一，而且我认为我们在此招聘的团队的才能和我们在世界其它任何地方所招聘的任何团队一样优秀。

从开发的角度来说存在不同，是因为中国的监管制度很不同。批准期较长，而且没有一个公平竞争的环境。本地公司和外国公司所受的对待不同。领先的本地公司的项目可以得到优先顺序，这样可以帮助它们更快地通过监管制度。如果你对在中国进行药物开发感兴趣，成为一家领先的本地公司十分重要，因为这样你会处于有利地位。因此，我们百济神州的做法就是建立一个是本地公司的组织，而且该组织要完全符合中国想做的事情。这也正是我们认为在中国当前监管制度框架内正确的方法。

另外一个不同是中国的人很多，你可很快地积累起临床试验病人的数量，而且成本只是美国或欧洲成本的一小部分。最后一点，是中国国家食品药品监督管理局对安全的重视。中国与临床试验相关的安全限制可能比其它国家要高得多。

问：中国目前的监管环境是有助于还是阻碍如象百济神州这样的公司进行药物开发？

答：中国目前的监管环境总体上是阻碍着这一行业的发展。那不是恶意的，而且有其合理的原因。目前，中国国家食品药品监督管理局还没有能力广泛地开放，提供一个人人均等的竞争环境。审查人员确实不足。因此，他们仅让少数人通过，从他们的角度来说，那些少数人应该就是领先的本地公司。我们认为，作为一个致力于重要项目的中国本地公司，我们可以通过使项目获得优先考虑来有利地运用目前的监管制度。但是我的确认为国家食品药品监督管理局要扩大其审查能力，继续作为一个机构来发展，作为一个组织从而提供一个公平竞争的环境，这对整个行业来说非常重要。国家食品药品监督管理局正在发展之中。如中国其它事情一样，今天的情况与五年前相比真是天壤之别，我预期今后五年和现在相比也会很不同。

问：去年，百济神州和杨森制药公司签订了共同开发和许可协议。对寻求与中国本地公司合伙共同进行药物开发的美国生物技术公司，您有什么建议？对寻求与美国生物技术公司建立合作伙伴关系的中国公司，您有什么建议？在美国和中国的药物研究公司进行共同开发安排方面，要避免哪些常见的陷阱？

答：对寻求与中国本地公司合伙共同开发药物的美国生物技术公司，我的主要建议是，始终要对与你合作的人持谨慎态度，重视你的合作伙伴的品质和文化，确保你们有一致的利益和经济观。这条建议适用于任何地方的项目，但是当你与某个世界另一端的人建立合作伙伴关系，而且是一个跨文化的合作伙伴关系时，就存在很多误会和误解的空间。你必须注意你的合作伙伴的声誉。中国的许多人会知道你的合作伙伴是谁，而且你的合作伙伴会有一个好或者坏、诚实或者不诚实、素质高或者不高的名声。而且每次在中国与其他人谈事时，你都要带着你的合作伙伴一起参加。

对寻求与美国生物技术公司建立合作伙伴关系的中国公司，我的建议是建立一个美国公司尊重并且信任的团队，这意味着你必须招聘恰当的人员并且以使你有吸引力的方式向他们提供报酬。我想，很多情况下，让中国公司这样做并理解为何这样做是很困难的。那是一笔很大的投资。但是，坦白地说，如果你想和美国公司建立合作伙伴关系，那是必需的。

问：位于中国的药物开发公司在融资方面的前景如何，如在从风险基金获得融资方面？目前，投资者和创始人应对并购退出或上市有何预期？

答：对设在中国的向西方风险资本公司筹资的药物开发公司来说，你需要建立一个西方公司尊重并且使他们感到容易相处的团队。没有精良团队的中国公司不可能从西方市场获得资本。但是存在各种于中国本地设立的基金。我的确认为，你会看到许多西方世界不愿意向其提供资金的人却能够在中国得到资金支持。中国基金认识他们，理解他们，并信任他们。

我认为前景是不错的。从和记黄埔和贝达药业等公司已经能看到中国出现了良好的信号。如果你回顾一下过去10年来的投资，主要是投向了CRO领域，我想如果你在由离岸资金投资的合法风险资本公司所投资的每一家公司都投入了1,000美元 ，你获得的回报将肯定超过所投资本的三倍，并且有可能接近四倍或者五倍。这种回报超过了中国大多数的风险投资者，无论是在生物技术行业与否。在这一领域运作的公司数量还有限，因此存在大的机会。

对于投资者和创始人对有可能进行

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Q&A

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And they're controlled to some degree by the government and the government will make sure that they continue to grow. I think you'll also see massive consolidation because the government has stated that it wants consolidation. In terms of IPOs for biotech companies, I think that the potential is there, and the onus is on the first set of companies that do go public to be successful. If they're successful and provide IPOs with attractive returns to investors over the next five years, the five years after that will be very big. The onus is on first-up companies to do a great job and make their investors a lot of money. I think that will happen.

Q: How has China's health care reform affected pharma in China, and in particular, drug development?

A: In terms of drug development, the SFDA continues to evolve in a way that is helpful and continues to reduce barriers and inefficiencies, but most of the health care reform in China has been centered around financial funding of research and development, and financial funding of health care in terms of hospitals and services to the general public. I think that in the next five years China will look at how to translate those investments in early-stage research into biology discovery.

Q: BeiGene focuses on cancer treatment drugs. What are some other areas for drug research in China that you see as a potentially untapped market? Do you see any key trends for drug development in China for 2012 and beyond?

A: People talk a lot about infectious diseases and STDs. There are a lot of people in China with hepatitis. I think that those are two areas that will see a lot of development, and there are already a lot of people moving down those paths.

More generally, the next big trend for drug development in China will be about showing that you can get innovative drug discovery and good biology from scratch. Another key trend is going to be opening up reasonable access to clinical development paths through a few trusted organizations.

Q: Tell us what you are currently most excited about with BeiGene's development, and why you're excited.

A: I'm most excited about our team. We have a world-class research team that has already had fantastic preclinical success. From a development perspective I think that our oncology development is on par with any organization in the world. We just happen to be in China. And we just happen to be focused on China and Asia. And I think that our oncology development team gives us the ability to bring in a handful of great assets and push them forward in a way that creates value and can help us build an organization from scratch that in a short period of time can be public and a multimillion dollar company. I think that we've already made a good start with the deals that we've done with Janssen and with Merck, and they're only the first two deals. We're currently looking to do two or three more, and I think that by bringing those deals together we have an organization with a very high expected value and a broad enough portfolio that it can be quite successful.

Trends and Best Practices in R&D Strategic Partnerships in China

By Julian Thurston, Thomas Chou, and Gordon Milner

Most of us engaged in the pharmaceutical, biotechnology, and medical device industries in the U.S. and Europe are well aware of the seismic changes occurring in the worldwide marketplace in these sectors, driven by the relentless pressure from most governments for cheaper and cheaper pricing of generics. Almost daily, there are reports of the occurrence of this from countries including, recently, Germany, Spain, the U.S., China, and other locations. In contrast, other changes are only occurring on a regional basis, such as the downsizing of sales forces in the U.S. and Europe, countered by a significant increase in sales forces in the Asian markets, particularly China. Where changes are regional, there is the possibility of arbitrage, and here we propose to examine the possibilities for this in the area of research and development in these sectors.

Leaving to one side the investment of the major pharmaceutical companies in R&D (and in many such companies there have been cutbacks in R&D spending either in terms of absolute financing numbers or as a percent of revenue over the past several years), there has been a growing realization, first in Europe and now in the U.S., that 10-year venture capital investment funds are not always appropriately suited for investment in companies focused on earlier-stage pharmaceutical or biotechnology R&D. If the history of investment in the sector from such funds in the U.S. and Europe is closely examined over the past 10 – 15 years, one can see that many did not meet their investment expectations and projected IRRs. The venture capital community investing in earlier-stage pharma R&D has been decimated in Europe and, to a lesser extent, in the U.S., with the exception of a small number of specialist venture capital firms with a track record of excellent exits, and even they are finding it as difficult as it has ever been to raise new funds. This has caused a crisis in the funding of earlier-stage R&D, and, although the pharmaceutical majors are aware of this and need collaborative partnering more than ever to bolster their pipelines, they cannot fill the void created by this harsh financing climate. There are some examples of the major pharmaceutical companies striking alliances with universities or other institutions doing

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人物简介

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的兼并或上市的现实预期而言，我认为将会有更多的向中国进行销售的制药公司以及中国的保健服务提供商进行上市。这些是一直在增长的行业。而且在一定程度上它们已经被政府所控制，政府将会确保它们继续增长。我想你还会看到大规模的合并，因为政府声明想要促进合并。就生物技术公司上市而言，我想潜力是有的，关键在于真正上市的首批公司是否取得成功。如果它们成功了并且在IPO上市接下来的五年里向投资者提供可观的回报，之后的五年潜力会很大。关键就在于首批上市的公司要表现得很好，为投资者赚很多钱。我想那是会发生的。

问：中国的医疗保健改革如何影响中国的制药行业，尤其是药物开发？

答：就药物开发而言，国家食品药品监督管理局一直在向有益的方向发展，并且不断减少障碍和无效率的情况，但是中国多数医疗改革都是围绕提供研发资金支持，以及在医院和公众服务方面提供医疗保健资金支持进行的。我认为未来五年中国将寻求如何将对早期研究的投资转化为生物发现。

问：百济神州致力于开发治疗癌症的药物。您认为还有哪些药物研究领域是潜在的未开发市场？您认为在2012年及今后中国药物开发主要有什么趋势？

答：人们经常讨论传染病和性传染病。中国有很多人患有肝炎。我认为这是两大具有发展潜力的领域。而且已经有很多人向那个方向迈进了。

更普遍说来，中国药物开发的下一个大趋势将会是证明你可以从零开始获得创新性的药物发现和优秀的生物科学。另一个主要趋势是通过为数不多的几家可以被信赖的机构开放对临床开发路径的合理使用。

问：请告诉我们您目前对百济神州的发展感到最兴奋的是什么，以及您兴奋的原因。

答：我最感到兴奋的是我们的团队。我们拥有一个世界级的研究团队，已经在临床前研究方面取得了极大的成功。从开发的角度来说，我认为我们的肿瘤学开发不亚于世界上的任何组织。我们只是恰好设在中国。我们只是恰好以中国和亚洲为重点。我想我们的肿瘤学开发团队使我们有能力注入一部分重要资产并向前推进，从而创造价值并且帮助我们从零开始建立一个组织，它能在短时间内上市并成为一个价值数百万美元的公司。我想，通过与杨森公司和默克公司签订的交易，我们已经有了一个良好的开端，但这仅是头两笔交易。我们目前还有望做另外两、三项交易。我想，把这些交易综合起来，我们就有了一个期望价值很高、项目组合足够广泛的组织，这个组织将会取得巨大成功。

中国研发战略合作伙伴关系的趋势和最佳实践

作者：Julian Thurston, 周至恒, Gordon Milner

我们在欧洲和美国从事制药、生物技术和医疗器械行业的多数人都明显意识到，这些行业部门的全球市场正在发生巨大的变化，究其原因是多数政府不断施压这些行业，迫使其不断下调非专利产品的定价。几乎每天都会有来自世界各地的新闻报道类似事件，包括最近从德国、西班牙、美国和中国等地传来的报导。相比之下，还有一些变化仅仅发生在地区层面上，比如：美国和欧洲的销售队伍呈缩减态势，而亚洲市场尤其是中国却呈现出销售队伍的大幅增长。由于这种变化的地区性特点，因而存在套利的可能性，在此我们建议在这些行业部门的研发领域对这种可能性进行调查。

抛开主要制药公司在研发方面的投资(很多此类公司过去几年来无论是在绝对融资数量还是占收入的百分比，研发费用都已有所削减)，先是欧洲、现在是美国，开始意识到十年期风险资本投资基金并不总是适合投入专注于制药或者生物技术早期研发的公司。如果仔细审视一下过去10-15年间美国和欧洲的此类基金在这个行业部门的投资历史，就可以看出许多基金并没有实现它们的投资预期和

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very early-stage research, one recent example being the partnership between the University of California, San Francisco, and Abbott Diagnostics. But generally speaking, there has been a serious decline in the funding of translational research in Europe and the U.S.

Although the emerging markets, and especially the BRIC countries, are demonstrating rapid annual growth in the size of their pharmaceutical markets, caused by a heady mix of rising middle-class affluence, a desire for better health care, the treatment of newly prevalent noncommunicable diseases arising due to changes in lifestyle, and, in some communities, the problems of a significantly aging population (e.g., China and Japan), this has not yet really driven significant investment in earlier-stage pharma R&D. Indeed, in many of these locations there is a desire by local and international companies to acquire the rights to "ready-to-go" assets that have marketing approval in the U.S. or Europe and can be made available in these new markets relatively quickly, possibly with a small level of additional clinical trials. In addition to the focus on "ready-to-go" products, there is also considerable interest in the broad bio-similar/bio-better space because of the extremely high prices being paid by emerging-market governments for the existing incumbents supplying blood products such as Factor VII or high-price monoclonal antibodies products such as Herceptin or HUMIRA. The Latin American and Russian focus is on stimulating local manufacture and providing incentives for such manufacturing initiatives. For example, in the deal conducted by GlaxoSmithKline (GSK) for vaccines in Brazil, GSK was given preferential long-term supply agreements in the Brazilian market in return for considerable technology transfer by GSK of its vaccines-manufacturing technologies.

There is, however, one market where there is a stand-out difference, and that is China. The Chinese government is vigorously pursuing policies and implementing long-term funding arrangements to promote the conduct of earlier-stage pharmaceutical R&D in China, with the ambition of transitioning from "Made in China" to "Discovered in China" (for China and the rest of the world). Indeed, both biotechnology and intellectual property research have been identified as "Strategic Emerging Industries" in China's 12th Five-Year Economic Development Plan (2011 – 2015), which calls for heavy government and private investment by Chinese enterprises to promote "indigenous innovation" in the fields of innovative biotech products, high-end medical devices, and patented medicines, coupled with a major modernization of China's health care and pharmaceutical distribution industries.

. . . ALMOST UNIQUELY IN RELATION TO CHINA, THERE IS THE POSSIBILITY TO STRIKE DEALS MARRYING WESTERN PRODUCTS AND TECHNOLOGIES WITH CHINESE PARTNERS AND FINANCIAL INVESTMENT.

Therefore, almost uniquely in relation to China, there is the possibility to strike deals marrying Western products and technologies with Chinese partners and financial investment. The Western products can either be a company's lead product—where it needs contribution of finance to conduct expensive clinical trials—or it can be in relation to technology that is perfectly good but effectively "on the shelf" for want of investment dollars. The U.S. and Europe are awash with such products and technology that have reached a certain point of development but that have been shelved in some sort of portfolio review. There is a growing realization amongst mid-sized life science companies in the U.S. and Europe that it is possible to do deals in China for pharmaceutical R&D at an earlier stage than in most other emerging markets, and we predict a wave of such deals over the coming years, driven by the deficit of financing of early-stage R&D in the Western markets, combined with R&D development lag time in this area facing the leading Chinese companies. These Chinese companies have distribution networks in place to penetrate the growing Chinese market for health care spending, but lack a pipeline of value-added products and technology. Although the last few years have seen a steady flow of Chinese-born but Western-educated research talent back to China (the so-called "sea-turtles"), the very long lead-in times required to produce mature products mean that they are facing a 10 – 15 year period of R&D to develop solid pipelines and fulfill local R&D and innovation targets. To meet their aspirations (and the 12th Five-Year Plan), these Chinese companies need to build pipelines at various stages of development fast, just like the Western major pharmaceutical companies, and an ideal way to do it is by the acquisition of the rights to Western products and technologies.

This trend of strategic partnering between Western companies and Chinese partners and investors is at its inception. We have been advising in some of these pioneering deals and are pleased to offer our readers some of our observations of the best practices for getting these transactions done.

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中国研发战略合作伙伴

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预期的内部收益率。除了少量的具有优秀业绩记录的专业风险资本公司外，投资于早期制药研发的风险资本社区在欧洲大规模减少，在美国稍轻一些，但即使是这些专业公司也感到募集新的资金前所未有的困难。这引发了早期研发投资的危机；尽管主要的制药公司意识到了这一点并需要比以往更多的协作伙伴关系来支持其渠道，但他们也无法填补这种严酷的融资环境而造成的这种缺口。现在有一些主要制药公司与大学或者其它机构结成联盟进行非常早期研究的事例，最近的一个例子就是位于旧金山的加利福尼亚大学和雅培诊断公司(Abbott Diagnostics)建立了合作伙伴关系。但总的来说，欧洲和美国的转化研究投资已经出现了严重的下滑。

尽管新兴市场，特别是金砖四国(巴西、俄罗斯、印度和中国)，由于中产阶级财富增长、要求更好卫生保健的愿望、治疗因生活方式改变而引发的新的流行性非传染疾病以及某些社会中日益严重的人口老龄化问题(例如中国和日本)等的综合原因而表现出制药市场年增长率快速提高的情况，但是这并没有真正驱动对制药业早期研发的大幅投资。的确，在很多此类地方，本地公司和国际公司都有一种购买“现成”资产权利的欲望，这种“现成”的资产在美国或者欧洲都已获得销售许可，在新兴市场可能通过少量的附加临床试验后，也能很快地进入市场。除了专注于“现成”的产品外，它们对广泛的生物仿制药品/优于原药药品领域也有相当大的兴趣，这是因为新兴市场的政府为现有的供应血液产品如Factor 7蛋白或者高价单克隆抗体产品如赫赛汀(Herceptin)或者修美乐(HUMIRA)的供应商支付极高的价格。拉美和俄罗斯的重点是刺激当地生产和对其提供奖励。例如，在格兰素史克(GSK)公司进行的巴西疫苗交易中，巴西给予了格兰素史克公司在巴西市场长期供应的优惠协议以换取该公司大规模转让其疫苗制造技术。

> …几乎唯有在中国，西方产品和技术才有可能与中国的合作伙伴和金融投资联姻达成交易。

然而，有一个市场与众不同，那就是中国。中国政府正在大力推行促进中国早期制药研发的政策并且实施相关的长期投资安排，雄心勃勃地推动由“中国制造”转变为“中国发明”（对于中国和世界其他地方而言）。的确，生物技术和知识产权研究都被确认为《中国第十二个五年经济发展规划》(2011-2015年)的“新兴战略产业”，“十二五”规划要求中国企业进行大量的政府和民间投资，以促进在创新性生物技术产品、高端医疗器械和专利药物的“本土创新”以及重点实现中国卫生保健行业和制药销售行业的现代化。

因此，几乎唯有在中国，西方产品和技术才有可能与中国的合作伙伴和金融投资联姻达成交易。西方的产品可以是一个公司的领先产品—这需要出资进行昂贵的临床试验—也可以是完好的、但因为缺少投资资金而被实质上“束之高阁”的技术。美国和欧洲有很多这样的产品和技术，它们已经达到某个开发的高点，但却被搁置在了某种专案审查中。美国和欧洲越来越多的中型生命科学公司意识到有可能在中国进行相较于其它的新兴市场更早期制药研发的交易，我们预测，由于西方市场早期研发资金不足加之中国领先的公司在这一领域面临研发滞后，未来几年会出现此类交易的浪潮。这些中国公司拥有到位的分销网络，可以渗透进中国不断增长的卫生保健市场，但是它们缺乏有附加值的产品和技术。尽管近几年来在中国出生但在西方国家接受教育的研究人才稳步地回流中国(所谓的“海龟”)，但是生产成熟产品所需要的相当长的起步时间意味着他们要面临10-15年的研发周期，才能开发可靠的渠道和实现本地研发和创新的目标。为了实现它们的渴望(和第十二个五年规划)，这些中国公司需要像西方主要的制药公司一样，快速地建立起不同开发阶段的渠

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R&D Partnerships

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Identifying the Partners: The Role of Intermediaries

Some of the largest Chinese pharmaceutical companies, especially the pharmaceutical arms of key State Owned Enterprises (SOEs), are still organizing themselves to conduct international business development, including establishing business development groups with English-speaking capabilities and developing intellectual property departments, licensing departments, and other assets necessary to conduct international transactions. At present, they do not tend to participate in international partnering sessions in force, nor even to attend partnering sessions in China that are largely conducted in English. Therefore, accessing these companies who want to do deals can be difficult. Generally, it is better, for the time being, to approach these companies through an intermediary with Chinese-language capability. Obviously, the intermediary needs to know the decision makers at these companies and their decision-making processes. Many intermediaries claim to know many of the key players, but the reality is that their contacts may not be with the right people within the organization, or the contacts may be superficial. Therefore, to establish good contact, it will be important to carefully research the potential intermediaries, and to use two or three intermediaries in order to triangulate on the right persons in such organizations. With the right intermediary, the whole process of communication between the Western rights owner and the Chinese company may be greatly facilitated. Realizing this, some of the key intermediaries are seeking remuneration through finder's fees or other success-based compensation, along the lines of boutique investment banks.

Quite clearly, it is necessary to approach Chinese companies with interest in the relevant technical area. Some Chinese companies are more small-molecule driven, others more biologic- or medical-device driven. We deliberately refer to "interest" here rather than experience, because a particular Chinese company may have a strategy for investment in a particular type of technology that is prevalent in the West, but has no real presence or availability in this area in the Chinese market as yet. An important component of these deals is that the Chinese companies are very anxious to learn, and so a high level of ongoing technology transfer is required, along with assistance with the design and conduct of preclinical and clinical trials. Armed with the design, the Chinese companies are more than willing to organize trials to be carried out at Chinese centers, because this takes them up the experience curve.

IN OUR EXPERIENCE, IT IS ADVISABLE FOR THE PARTIES TO TRY AND WORK UP A BUSINESS PLAN, INCLUDING THE PLAN AND BUDGET FOR THE CONDUCT OF THE RESEARCH AND DEVELOPMENT ENVISAGED.

Identifying Contributions and Financing Needs

Just as in any transaction, once there are interested potential partners, this leads to discussions about the nature of the opportunity. In our experience, it is advisable for the parties to try and work up a business plan, including the plan and budget for the conduct of the research and development envisaged. Agreeing in some detail what is required to get the products onto the Chinese market, how long it will take, its phases (e.g., import initially, with a local manufacturing capability established later), and what will be the contribution of the parties (including the financial contribution) are key components of these deals. There are likely to be many contributions in kind, with the Western company providing intellectual property, technology transfer, and possibly some equipment, and the Chinese party providing resources, such as land and/or buildings, manufacturing capabilities, distribution networks, and/or financing.

This planning exercise will also focus minds on the financing required to achieve the strategic goal. If, on a gap analysis, it appears the project requires more investment than the parties are willing to contribute, this will identify the need for the involvement of third-party investors. There are a number of private equity, venture capital, and strategic investor groups in China that are anxious and willing to participate in these projects.

Working Through Transaction Structure Drivers

As much as it is commercially desirable to agree upon the relative contributions of both parties, the form and magnitude of the contributions (e.g., cash vs. in-kind consideration) will help inform the ideal structure of the proposed transaction, as well as the government approvals that will be required in order to implement such a transaction. In addition to the type and magnitude of the contributions being made by each party, the specific characteristics of the Chinese partner (e.g., private vs. publicly traded, onshore vs. offshore incorporated, SOE vs. private sector), and the specific technologies being developed (e.g., whether they are activities that are encouraged, permitted, restricted, or prohibited for foreign investment in China), may dictate the recommended structure of the strategic transaction. In this regard, it is important to be aware that

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道，而这样做的理想途径是收购西方产品和技术的权利。

西方公司和中国合作伙伴及投资者之间的这种战略合作伙伴关系才刚刚开始。我们一直在对其中一些开创性的交易提出建议，并且乐于把我们观察到的最佳实践提供给读者，以达成这些交易。

寻找和确定合作伙伴：中介的作用

中国的一些大型制药公司，特别是重点国有企业(“国企”)的制药部门，仍然在组织进行国际业务开发，包括建立具有英语能力的业务开发小组和发展知识产权部门、许可部门以及进行国际交易必需的其它技能。现在，他们不会去参加现存的国际合作伙伴关系会议，甚至不参加主要用英语进行的中国合作伙伴关系会议。因此，要接近这些想做交易的公司会很困难。一般来说，目前接近这些公司比较好的方式是过具有中文语言能力的中介机构。很明显，中介机构需要了解和熟悉这些公司的决策者以及他们的决策过程。许多中介机构声称他们认识许多重点企业的人物，但事实上与他们建立联系的人员可能并非是组织内的关键人员，或者这种联系可能是表面性的。因此，要建立良好的联系，重要的是仔细研究潜在的中介机构并且使用两、三家中介机构，以便从多视角确定上述组织内的关键人员。有了恰当的中介机构，就可以极大地促进西方权利所有人和中国公司之间的整个沟通过程。意识到了这一点，一些主要的中介机构会按照小投资银行的规定以介绍费或者其它基于成功度而设定报酬的方式收取报酬。

很明显，去接近那些对相关技术领域感兴趣的中国公司是十分必要的。有些中国公司的业务重心更倾向于小分子药物，而另外一些则更倾向于生物或医疗器械。我们在此有意地提到“兴趣”而不是经验，这是因为某个公司可能对在西方盛行但在中国市场还没有真正出现的某种类型的技术制定投资战略。这些交易的一个重要组成部分是中国的公司非常急于学习，因此，进行高水平的现行技术转让时，需要一并提供与设计和进行临床前试验和临床试验有关的帮助。有了这种设计，中国公司会非常愿意在中国各地的中心组织开展试验，因为这提升了他们的经验值。

> 根据我们的经验，各方最好是尽力制定一个商业计划，包括未来进行研究和开发的计划和预算。

确定出资和融资需要

和任何交易一样，一旦有了感兴趣的潜在合作伙伴，就会对交易机会的性质进行有关的讨论。根据我们的经验，各方最好是尽力制定一个商业计划，包括未来进行研究和开发的计划和预算。使产品进入中国市场需要做什么、需要多长时间、需要的各个阶段(比如首先是进口，然后是建立本地制造能力等)以及各方用什么来出资(包括金融出资)是这些交易的主要组成部分，需要在细节上达成一致。很可能会有许多实物形式的出资：西方公司提供知识产权、技术转让以及可能提供部分设备；中国一方提供资源比如土地和/或厂房、制造能力、分销网络和/或融资。

这种计划演习还要集中于实现战略目标所需要的融资。如果，根据缺口分析，项目需要的投资额似乎超过了各方愿意的出资额，这就要确认第三方投资者参与的必要。中国有大量的私募股权、风险资本和战略投资集团急于并且愿意参与这类项目。

完成交易结构部分

尽管最好是在商业上就双方的相关出资要达成一致，但是出资的方式和大小(比如现金相对于实物考量)会有助于获知拟定交易的理想结构以及为执行这一交易而需要的政府批准。除了各方出资的方式和大小以外，中国合作伙伴的特别性质(比如是私有还是公开交易、是在岸组建还是离岸组建、是国有部门还有私人部门等)以及正在开发的特

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R&D Partnerships

(Continued from Page 10)

Chinese law places strict requirements on the types of intellectual property rights that can be contributed, and the extent to which such in-kind assets can be used to fund the capital requirements of onshore entities. The complexity of the approval process and the time it may take should not be underestimated, and it may be desirable to the have some initial approval in principle even before the letter of intent is established, particularly if arms of local government are going to be providing a grant or other cash contribution to assist with the development of the project.

Due Diligence, Documentation, and the Pacing Items

There is a considerable amount of work to be undertaken before the documentation of a deal is sensibly generated. It is very common in these deals to aim first for a term sheet, letter of intent, or memorandum of understanding that sets out in some detail the nature of the project, the contributions of the parties, and their key objectives (e.g., achieving a given exit). In the discussion of the letter of intent, it is critical that allowance be made for a number of face-to-face meetings, possibly including the intermediaries we have mentioned, so that everyone becomes comfortable with each other. Sometimes, Chinese companies want the letter of intent to be binding and, although this is not customary for international transactions (with certain carveouts), it may be possible to mitigate the effect of accommodating such demands in relation to certain provisions (e.g., designating a short long-stop date, pursuant to which the letter of intent and its binding nature terminate if the definitive agreements have not been entered into by such long-stop date). Once the letter of intent is executed, there still needs to be time properly allocated to engaging in due diligence on both parties' proposed contributions, as well as a means of integrating the internal and external approval processes and generating the definitive agreements, which will almost inevitably generate timing issues due to the need to produce initial, interim, and final drafts of each agreement in both Chinese and English. In some cases, the Chinese party is not as experienced with these types of deals, and as it really begins to understand the proposed terms of the transaction in detail, it may well seek to renegotiate the terms of the transaction. In addition, the Western party (or certain groups within its organization) may not be familiar with Chinese foreign investment and technology import regulations. As a result, additional time and energy may be needed to educate and reach internal consensus on regulation-driven structures and terms, which may be more rigid and less favorable, respectively, than those adopted by the Western organization in its domestic or other international collaborations. There needs to be understanding on both sides about this. By this point, however, when the parties are feeling more comfortable with each other, more can be potentially handled through the exchange of drafts, and the need for face-to-face meetings may diminish. There must also be adequate time and resources set aside for government and third-party approval processes, many of which occur from the date the definitive agreements are signed until the closing of the proposed transaction.

IT IS VERY COMMON IN THESE DEALS TO AIM FIRST FOR A TERM SHEET, LETTER OF INTENT, OR MEMORANDUM OF UNDERSTANDING THAT SETS OUT IN SOME DETAIL THE NATURE OF THE PROJECT, THE CONTRIBUTIONS OF THE PARTIES, AND THEIR KEY OBJECTIVES . . .

Overall Timing

The message from all of this is clear—getting a deal done in China is going to take considerable time, commitment, and patience. For years now, business development folks have debated how long it takes to get these strategic partnering deals done in the West from inception to conclusion, and quite frequently it is in the region of 12 – 18 months. In relation to China, it is possibly a little longer, and so the Western rights holder wanting to announce a deal to sustain its share price and to bring in money for underutilized assets should be under no illusion that trying to carry out a deal in China will be a short-term panacea. Indeed, the Western company needs to have the commitment and drive to see things through. Over the next several years, we anticipate these timelines shortening as the Chinese companies get more and more experience with such deals.

In our next issue, we will further examine the details of these deals and look at some of the key structural, regulatory, and commercial issues parties face when negotiating these deals.

USPTO Proposed Rules on Preissuance Submissions

By Peng Chen and Kun Wang

On January 5, 2012, the U.S. Patent and Trademark Office (USPTO) published proposed regulations regarding preissuance submissions to implement part

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中国研发战略合作伙伴

(续第11页)

别技术(比如是否是被鼓励、允许、限制还是禁止的外国投资在中国进行的活动)可能决定着战略交易的拟定结构。在这一点上，重要的是要知道中国法律对可以当作出资的知识产权类型以及此类实物资产可以用于投资在岸实体的范围都设有严格的要求。批准过程的复杂性和批准所需要的时间也不应该被低估，最好的情况可能是在签订意向书之前就获得了原则上的初步批准，尤其是如果地方政府部门将会提供权利授予或者其它现金出资来帮助项目的开发。

尽职调查、文件和进度

在交易文件理智地产生出来之前，还有相当大的工作量要做。这些交易中，很常见的首先是投资条款表、意向书或者谅解备忘录，其中较为详细地列出了项目的性质、各方的出资以及他们的主要目标(比如实现一个既定的退出机制)。在讨论意向书时，关键是提供一定数量的见面会，可能包括我们上面提到的中介机构，这样大家就会变得彼此容易相处。有时，中国公司想要意向书具有约束性，尽管这不是国际交易的惯例(带有一定的例外)，但是它可能会减轻为适应某些规定要求(比如设定一个短暂的最后日期，如果在此最后日期前没有达成最终协议，则终止意向书及其约束力)而产生的影响。一旦签订了意向书，仍然需要妥当地安排时间对双方拟定的出资开展尽职调查，并想办法统一内部和外部的批准过程和生成最终协议，这将几乎不可避免地会造成时间问题，因为需要用中英文制定每个协议的初稿、修改稿和终稿。在有些情况下，中方对这类交易没有经验，当它真正开始详细地理解了交易中拟定的条款时，它很可能会要求对交易的条款重新谈判。另外，西方国家

这些交易中，很常见的首先是投资条款表、意向书或者谅解备忘录，其中较为详细地列出了项目的性质、各方的出资以及他们的主要目标...

的一方(或者组织内的某些团队)可能不熟悉中国的外国投资和技术进口规定。因此，可能需要更多的时间和精力对监管规定的结构和条款进行培训和达成内部一致，这些结构和条款与西方组织在其国内合作和其它国际合作中接受的相比可能更加严格并且不太有利。双方都需要理解这一点。然而，当各方都感到彼此容易相处时，更多的事情可以潜在地通过稿件交流的方式进行处理，见面会的需要会减少。还必须留出足够的时间和资源用于政府和第三方的批准程序，其中很多会自最终协议签署日起一直持续到拟定的交易结束。

总体时间

所有这一切传递的信息非常之明确——即在中国达成一项交易是需要相当多的时间、投入和耐心的。多年来，商业开发人士对在西方达成这类战略合作交易从开始到结束需要多长时间一直存在着争论，普遍的看法是大约需要12-18个月。而在中国，可能需要稍长一点，因此，想要宣布一项交易以维持其股价并且通过未充分利用的资产带来金钱的西方权利所有人不要幻想着在中国进行一项交易会是一剂短期的万能灵药。西方公司的确需要有决心和动力坚持到底。未来几年，随着中国的公司对这类交易越来越有经验，我们预期这些时间线会缩短。

在下一期中，我们将进一步探讨这些交易的细节以及各方在进行交易谈判时所面临的主要结构问题、监管问题和商业问题。

美国专利商标局提议制定专利颁发前呈报规则

作者：陈朋、王堃

2012年1月5日，为实施新制定的《莱西-史密斯美国发明法》(简称“美国发明法”)的部分规定，美国专利商标局(简称“美国专利局”)公布了提议制定的专利颁发前呈报法规。

美国发明法第8条对《美国法典》

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USPTO

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of the new Leahy-Smith America Invents Act ("AIA").

Section 8 of the AIA amends 35 U.S.C. § 122 by adding 35 U.S.C. § 122(e), which lists certain conditions that apply to a third-party preissuance submission to the USPTO in a patent application. According to 35 U.S.C. § 122(e), third-party preissuance submissions of patents, published patent applications, or other printed publications must be made in patent applications before the earlier of: (a) the date of a notice of allowance; or (b) the later of (i) six months after the date on which the application is first published, or (ii) the date of the first rejection of any claim by the examiner. Also required is a concise description of the asserted relevance of each document submitted, a fee, and a statement by the person making the third-party preissuance submission that the submission was made in compliance with 35 U.S.C. § 122(e). The provision takes effect on September 16, 2012, and applies to any patent application filed before, on, or after September 16, 2012.

Besides noting that 35 U.S.C. § 122(e) will be implemented as new rule 37 C.F.R. § 1.290, the notice also indicates that the current rule under § 1.99 will be eliminated. In comparison to the current rule, the new rule allows a third party to include a concise description of the printed publication being submitted, which does not need to constitute prior art. Further, the new rule provides a longer time frame for the preissuance submission.

Current Rule (Section 1.99)

The current rule does not permit an accompanying concise description and limits the time period for such submissions to up to two months after the date of the patent application publication, or mailing of a notice of allowance, whichever is earlier.

New Rule (Section 1.290)

Section 1.290(a)

Under the new rule, third-party submissions may be directed to nonprovisional utility, design, and plant applications, as well as to continuing and reissue applications. It does not require that the application be published.

UNDER THE NEW RULE, THIRD-PARTY SUBMISSIONS MAY BE DIRECTED TO NON-PROVISIONAL UTILITY, DESIGN, AND PLANT APPLICATIONS, AS WELL AS TO CONTINUING AND REISSUE APPLICATIONS. IT DOES NOT REQUIRE THAT THE APPLICATION BE PUBLISHED.

The new rule limits the type of information that may be submitted to patent publications, which includes patents and published patent applications, and other printed publications of potential relevance to the examination of a patent application. Submissions may not include unpublished internal documents or other nonpatent documents that do not qualify as "printed publications." *See Manual of Patent Examining Procedure (MPEP)* § 2128.

Because 35 U.S.C. § 122(e) does not limit the type of information to prior art, there is no requirement in § 1.290(a) as proposed that the information be prior art. Where a third party is asserting that a document is prior art, the third party bears the burden of establishing the date of the document where the date is not apparent from the document, regardless of whether the document is in paper or electronic format. The third party may submit evidence in the form of affidavits, declarations, or other evidence.

Section 1.290(b)

Submission must be filed before the earlier of: (1) the date a notice of allowance is given or mailed in the application; or (2) the later of: (i) six months after the date on which the application is first published by the USPTO under 35 U.S.C. § 122(b) and § 1.211, or (ii) the date the first rejection under § 1.104 of any claim by the examiner is given or mailed during the examination of the application. The time periods provided for in § 1.290(b) are statutory and cannot be waived.

The § 1.290(b)(2)(i) time period would be initiated only by publications by the USPTO under 35 U.S.C. § 122(b) and § 1.211, and would not be initiated by a publication by the World Intellectual Property Organization.

The proposed new § 1.290(b)(2)(ii) time period would be initiated by the date the first rejection under § 1.104 of any claim by the examiner is given or mailed during the examination of the application. The § 1.290(b)(2)(ii) time period would not be initiated, for example, by a first Office Action that only contains a restriction requirement or where the first Office Action is an action under *Ex parte Quayle*, 1935 Dec. Comm'r Pat. 11 (1935).

Section 1.290(c)

Section 1.290(c), as proposed, requires a preissuance submission to be made in writing. It can be a paper or an electronic filing. In either case, the third party will not receive any communications from the USPTO relating to the submission other than the self-addressed postcard or electronic acknowledgment of receipt. It also requires that the application to which the third-party submission is directed be identified on each page of the submission by application number (i.e., the series code and serial number), except for the copies of the documents that are being submitted pursuant to § 1.290(d)(3).

Section 1.290(d)

Section 1.290(d)(2), as proposed, requires a concise description of the asserted

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美国专利商标局

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第35篇第122条做了修订，新增第122(e)条，其中列明了对第三方在专利申请过程中向美国专利局进行专利颁发前呈报适用的某些条件。根据《美国法典》第35篇第122(e)条，在专利申请过程中，第三方在专利颁发前呈报专利、已公布专利申请或其他印刷出版物的时间必须在以下两个时间中的较早者发生之前：(a) 发行通知出具之日；或(b) (i) 从申请首次公布之日起满六个月，或(ii) 审查人员首次驳回任何权利要求之日（以较晚者为准）。该条还要求对宣称的所呈报各份文件具有的相关性做出简要说明，缴纳一定费用，并由进行第三方专利颁发前呈报的人说明呈报是根据《美国法典》第35篇第122(e)条进行的。该条规定自2012年9月16日起生效，适用于在2012年9月16日之前、当天或之后呈报的任何专利申请。

除指出《美国法典》第35篇第122(e)条将作为新添加的《联邦法规汇编》第37篇第1.290条实施以外，通知还表示第1.99条项下的现行规则将被废止。与现行规则相比，新规则允许第三方对所呈报的印刷出版物提供一份简要说明，并且印刷出版物未必构成现有技术。另外，新规则规定的专利颁发前呈报期限比原来长。

现行规则（第1.99条）

现行规则不允许随附简要说明，并将呈报的期限限制为从公布专利申请或邮寄发行通知（以较早发生者为准）之日起最多两个月。

新规则（第1.290条）

第1.290(a)条

根据新规则，第三方呈报可以针对非临时实用新型、外观设计和植物专利申请，也可以针对专利续延和再颁申请。新规则不要求专利申请已公布。

根据新规则，第三方呈报可以针对非临时实用新型、外观设计和植物专利申请，也可以针对专利续延和再颁申请。新规则不要求专利申请已公布。

新规则将可以呈报的资料类型限制为专利出版物（包括专利和已公布专利申请），以及可能与专利申请审查有关的其他印刷出版物。呈报的资料不得包括未公开出版的内部文件，或不符合“印刷出版物”条件的其他非专利文件。参见《专利审查程序手册》（MPEP）第2128条。

因为《美国法典》第35篇第122(e)条未将资料类型限制为现有技术，所提议的第1.290(a)条没有要求呈报的文件应为现有技术。当第三方宣称某文件为现有技术时，如果从文件（无论是纸质文件还是电子文件）上看不到明显的日期，该第三方就要承担证明文件日期的义务。第三方可以以宣誓证词、声明或其它证明形式提交证据。

第1.290(b)条

呈报的文件必须在以下两个时间中的较早者发生之前提交：(a) 申请过程中发出或邮寄发行通知之日；或(b) (i) 从美国专利局根据《美国法典》第35篇第122(b)条和《联邦法规汇编》第37篇第1.211条首次公布申请之日起满六个月，或(ii) 在申请审查过程中，审查人员根据《联邦法规汇编》第37篇第1.104条对任何权利要求做出的首次驳回决定发出或邮寄之日（以较晚者为准）。《联邦法规汇编》第37篇第1.290(b)条规定的期限是法定的，不可以豁免。

第1.290(b)(2)(i)条规定的期限只可从美国专利局根据《美国法典》第35篇第122(b)条和《联邦法规汇编》第37篇第1.211条进行公布时开始计算，不会从世界知识产权组织（WIPO）进行公布时开始计算。

提议新制定的第1.290(b)(2)(ii)条规定的期限可从申请审查过程中审查人员根据第1.104条对任何权利要求做出的首次驳回决定发出或邮寄之日开始计算。例如，仅包含限制要求的首份专利局审查决定书不会致使第1.290(b)(2)(ii)条规定的期限开始，或如果首份专利局审查决定是根据《1935年专利及专利局长和美国法院决定》（1935）中的“专利申请修改要求”做出的决定，该期限也不会开始。

第1.290(c)条

所提议的第1.290(c)条要求以书面形式进行专利颁发前呈报。呈报的文件可以是纸质的，也可以是电子形式的。无论在哪种情况下，除注明发信人自己地址供寄回的明信片或电子回执以外，第三方不会从美国专利局收到任何与资料呈报有关的

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relevance of each listed document. The concise description should explain why the respective document has been submitted and how it is of potential relevance to the examination of the application. Unless there is no concise description, or the concise description is merely a bare statement that the document is relevant, the USPTO does not propose to otherwise evaluate the sufficiency of the concise description. It would be a best practice for each concise description to point out the relevant pages or lines of the respective document, particularly where the document is lengthy and complex, and the third party can identify a highly relevant section, such as a particular figure or paragraph.

Section 1.290(h)

Section 1.290(h), as proposed, provides that in the absence of a request by the USPTO, an applicant has no duty to, and need not, reply to a submission under § 1.290. Likewise, no further response from a third party with respect to an examiner's treatment of the third party's preissuance submission would be permitted or considered.

Implications of the Proposed Rules on Preissuance Submission

Under the current rules, submissions of prior art by third parties are allowed, but they may not comment on the prior art. Many practitioners have been reluctant to submit prior art without the ability to comment, because it is possible that the examiners will not apply the cited prior art in the manner desired by the third parties. As a result, submissions of prior art by third parties in patent applications during *ex parte* prosecution are rare.

The new preissuance submission practice will allow third parties to submit prior art to the USPTO and provide concise explanations of relevance. In comparison to the reexamination proceedings and the postissuance procedures under the AIA, the new preissuance submission practice has a few advantages:

IT WOULD BE A BEST PRACTICE FOR EACH CONCISE DESCRIPTION TO POINT OUT THE RELEVANT PAGES OR LINES OF THE RESPECTIVE DOCUMENT, PARTICULARLY WHERE THE DOCUMENT IS LENGTHY AND COMPLEX, AND THE THIRD PARTY CAN IDENTIFY A HIGHLY RELEVANT SECTION, SUCH AS A PARTICULAR FIGURE OR PARAGRAPH.

First, the cost and burden of filing a preissuance submission is significantly less than that of postissuance procedures. The supplementary information accompanying the proposed rules suggests that no fee is required for the submission of three or fewer documents in a preissuance submission. A relatively small fee is required if more than three documents are submitted. The official fee associated with a preissuance submission is at most a few hundred dollars compared to thousands of dollars for postissuance proceedings such as *inter partes* reexamination.

Second, unlike reexamination proceedings, as well as the new postissuance review and *inter partes* review proceedings under the AIA, third parties submitting preissuance submissions can remain anonymous. Thus, it is possible to challenge the validity of an applicant's patent claims without fear of retaliation by the applicant.

Third, unlike reexamination proceedings, as well as the new postissuance review and *inter partes* review proceedings, there is no estoppel for later litigation.

Fourth, the grounds for filing a preissuance submission are not limited to prior-art-related challenges. For example, a preissuance submission may be filed on the grounds of patentable subject matter, written description, enablement, etc.

The only factor against filing a preissuance submission may be that reexaminations are conducted by the Central Reexamination Unit, which consists of examiners with more experience than the average examiner in the USPTO. Similarly, the new postissuance review and *inter partes* review proceedings will be conducted by the Patent Trial and Appeals Board with experienced administrative law judges.

Potential infringers having more modest means may choose a "preissuance submission" as a cost-effective way to limit eventual damage and to gain certainty. Given the cost-effective and anonymous nature of the proceeding and the lack of estoppel to future litigation, we expect more and more parties will engage in using preissuance submission as a first-line attack on competitors and part of the overall strategy on intellectual property. As a result, it will significantly change the current patent examination process, and make it a quasi-*inter partes* process.

美国专利商标局

(续第15页)

讯息。该条还要求在第三方呈报的每页文件上均用申请号（即序列编码和序号）注明第三方呈报针对的申请，但根据第1.290(d)(3)条呈报的文件的拷贝除外。

第1.290(d)条

所提议的第1.290(d)(2)条要求对宣称所列每份文件具有的相关性做出简要说明。简要说明应解释呈报各份文件的理由，以及该文件可能与申请审查相关的方式。除非没有简要说明，或简要说明仅表示文件是相关的，否则美国专利局不会提议另行评估简要说明的充分性。最好的办法是指出各份文件上有关的页面或内容，特别是当文件冗长、复杂时，同时第三方可标出高度相关的章节，例如具体图标或段落。

第1.290(h)条

所提议的第1.290(h)条规定，如果美国专利局未要求，申请人没有义务、也不需要对根据第1.290条进行的呈报做出答复。同样，不允许第三方就审查人员对第三方于专利颁发前所呈报资料的处理事宜做出进一步答复，也不会考虑第三方做出的进一步答复。

提议制定的专利颁发前呈报规则的意义

按照现行规则，允许第三方呈报现有技术，但他们不得对现有技术发表意见。许多从业者不愿在无法发表意见的情况下呈报现有技术，因为审查人员可能不会以第三方希望的方式运用所提出的现有技术。因此，在以“单方申请”进行审查时，很少有第三方在专利申请过程中呈报现有技术。

最好的办法是指出各份文件上有关的页面或内容，特别是当文件冗长、复杂时，同时第三方可标出高度相关的章节，例如具体图标或段落。

新制定的专利颁发前呈报措施将允许第三方向美国专利局呈报现有技术，并提供简要的相关性说明。与美国发明法项下的复审程序和专利颁发后程序相比，新制定的专利颁发前呈报措施有几点好处：

首先，进行专利颁发前呈报的费用和负担明显低于专利颁发后程序。提议制定的规则随附的补充资料显示，在专利颁发前呈报过程中呈报三份或三份以下文件不需要付费。如果呈报的文件超过三份，则需要缴纳相对较少的费用。与专利颁发前呈报有关的法定费用最多为几百美元，而专利颁发后程序（如“双方”复审）要花几千美元。

第二，与复审程序以及美国发明法项下新制定的专利颁发后审核和“双方”审核程序不同的是，进行颁发前呈报的第三方可以匿名。因此，可以在无需担心申请人报复的情况下，对申请人专利权利要求的有效性提出质疑。

第三，另外与复审程序以及新制定的专利颁发后审核和“双方”审核程序不同的是，对晚些时候的诉讼不存在禁止反言规定。

第四，进行专利颁发前呈报的依据不限于与现有技术有关的质疑。例如，可以根据可获得专利的标的、书面说明、可据以实施性等进行专利颁发前呈报。

唯一对进行专利颁发前呈报不利的因素可能是复审是由中心复审组进行的，而与美国专利局的普通审查人员相比，中心复审组的审查人员经验更丰富。同样，新制定的专利颁发后审核和“双方”审核程序将由专利审理和上诉委员会进行，而该委员会是由经验丰富的行政法法官组成的。

囊中羞涩的潜在侵权者可通过“颁发前呈报”来以低廉的费用限制最终损害，并得到确定的答案。鉴于该程序所需费用较低，允许匿名，且对将来诉讼没有禁止反言规定，我们预期会有越来越多的人将专利颁发前呈报用作对竞争对手的首轮打击手段及总体知识产权战略的一部分。因此，专利颁发前呈报将显著改变现行的专利审查程序，并使其成为一种“准双方”程序。