China Life Sciences 中国生命科学通讯 Newsletter

Welcome to the inaugural issue of our China Life Sciences Newsletter, a periodic update on key developments, companies and people in the dynamic China life sciences industry. The goal of the newsletter is to provide companies, entrepreneurs and investors with useful information on the issues and opportunities most relevant to China life sciences businesses.

Our issue opens with an Investor Q&A piece with Dr. Leon Chen of Fidelity Growth Partners Asia. Dr. Chen's experience spans the research laboratory, management consulting, and most recently, life sciences venture capital industries. Dr. Chen reviews notable trends and opportunities in the med device sector in China. Next is an article by a Morrison & Foerster patent partner Peng Chen addressing implications of the Leahy-Smith America Invents Act specifically for Chinese life science companies, including the need to reevaluate patent application filing strategies and policies regarding public disclosure of inventions in view of the shift to first-to-file, and amendments to the test for what is considered prior art under U.S. patent law. Finally, we also feature in this inaugural issue an article highlighting key points to consider when acquiring a Chinese life sciences company, and a brief note on regulatory developments of interest.

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.

欢迎阅读我们的第一期中国生命科学通讯！通讯将定期对中国生机勃勃的生命科学产业的关键发展、公司及专业人员的相关信息进行更新报道，其目标是针对与中国生命科学行业息息相关的事务和机遇，为公司、企业家及投资者提供实用信息。

本期开篇文章为富达亚洲风险投资合伙人陈连勇（Leon Chen）博士撰写的《投资者问与答》。陈博士的经验涉及研究工作实验室、管理咨询和最近兴起的生命科学风险投资等。陈博士对中国医疗器械行业的重要趋势和机会作出了点评。第二篇文章来自美富律师事务所专利合伙人陈朋，文章指明了《美国专利改革法案》对中国生命科学公司的意义，包括在转向"先提交先保护制度"后对专利申请提交战略和与披露发明有关的政策重新进行评估的必要性，以及在美国专利法项下对视为现有技术的评判标准的修订等。

最后，在本期通讯中，我们还推出一篇文章，对在收购中国生命科学公司前需要考虑的关键因素进行重点阐述，以及简述相关的监管发展。欢迎向我们提出您的想法和意见—如有对将来的主题有任何要求或建议，请发电邮予编辑柯弥律师、周至恒律师或陈朋律师。

此致

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Investor Q&A

Profile: Leon Chen, Partner, Fidelity Growth Partners Asia

Dr. Chen joined Fidelity Growth Partners Asia in 2008. He has more than 15 years of experience as an accomplished scientist, management consultant, and venture capitalist. Prior to joining Fidelity, Dr. Chen was a managing partner at BioVeda China. Since 2005, Dr. Chen has been one of the most active investors in China in the life sciences sector, and has led a number of investments in the fields of drug discovery and development, drug distribution, medical devices, vaccines, therapeutic antibodies and industrial biotechnology.

From 1997 to 2005, Dr. Chen was a management consultant and a business adviser to pharmaceutical and biotech companies. He worked as a management consultant with McKinsey & Company and Ernst & Young LLP and as a co-founder and managing partner with Life Science Strategic Consulting in the San Francisco Bay Area. From 1993 to 1997, Dr. Chen worked as a research scientist at Schering-Plough in New Jersey. His research experience includes working as a member of the discovery team of Vytorin/Zetia, which is now a multibillion-dollar drug.

Dr. Chen received a Bachelor of Science degree from Peking University and a Ph.D. with top honors in organic chemistry from Catholic University of Louvain, and was a post-doctoral fellow at the Massachusetts Institute of Technology. He holds six issued U.S. patents and co-authored the 14th and 15th Ernst & Young Biotechnology Reports.

Q: What do you see as the main characteristics of the medical device and IT health services markets in China currently? Who is winning, and why?

A: It's important to distinguish between medical devices and health IT.

Health IT has been managed by the PRC government from the very beginning. Under the current health care reforms announced in China's Twelfth Five-Year Plan, China's health data system is being digitized. Currently, patient histories for the most part exist only in hard-copy form. This makes it very difficult for doctors to easily locate and review patient records. The government is organizing the information on a broad IT platform. Since most hospitals are still owned by the government, as digitization occurs, it should proceed relatively rapidly. Private hospitals are a recent movement. Some international players have recently gotten into the sector.

The medical device sector is flourishing. As many readers are aware, all of the established global players for X-ray and MRI equipment, including GE, Philips and Siemens, have been in China for over 10 years. These companies are still winning because they have invested heavily in the system and have established brand names. They also provide training to the doctors and good post-installation support.

Chinese companies have found a way to take over the market for smaller equipment, such as ultrasound, biochemistry analysis, patient monitoring systems and lower-end imaging systems. Mindray is doing well, as is Edan Medical. There are probably two or three other players in the same category. Domestic companies are somewhat favored in this space. At the same time, the quality of the locally made products is becoming more and more reputable. Labor costs are significantly lower, so companies with local manufacturing are able to sell comparable domestic med device products at a price point 30 percent below imported products.

Q: What are the hot areas for medical device and IT health services investments or partnering?

A: Lab diagnostic analyzers, blood chemistry and cancer diagnosis are hot right now.

The total market size for these sectors is between $1 billion and $1.5 billion. The market is growing 20 percent, year on year. Roche, Abbott and others have been in China for a long time, and are heavily invested in the medical community. People know about them and consider their products as the gold standard. That said, they are also expensive. We see no major local players in this space yet. There are fewer than five players developing and manufacturing products in these sectors domestically. Everyone knows that the quality does not match that of imported products, but their products are used by the public hospitals and especially have a heavy presence in government-sponsored general screenings, for instance, for hep B, and often in smaller cities. They are good enough and serve a purpose.

The large equipment market is difficult. There is a lot of competition, and once a system is installed, it takes five- to 10-years to replace it.

The orthopedic area is also active—meaning artificial knees and spinal products.

According to a Morgan Stanley research note, the orthopedic implant market is growing at a robust pace of 18 percent CAGR. It is projected to become the second largest market in the world by 2015. Low implantation rates of trauma, spine and joint products leave significant potential for future growth. The growth is driven by rising disposable incomes, aging population and expanding insurance coverage. We also see opportunities in trauma. With all the urban construction going on, there are a lot of accidents.

The exception for growth of imported products is artificial joints. Chinese companies can make titanium plates and screws. Local companies will copy imported products or find the right people to make them. Penetration of these products by foreign players in China is still low.

One overall caveat: there is an issue as to what people will pay for quality of health care. The health care services consumer in China generally does not want to spend a lot of money—true everywhere, right? A locally made device can be as good at half the price as an imported one. The cost of surgery in China is much lower than in the U.S., but there are hidden costs. Doctors still accept "red

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投资者问与答

简介：陈连勇，富达亚洲风险投资合伙人

2008年，陈博士加入富达亚洲风险投资。作为卓有成就的科学工作者、管理顾问和风险投资专家，他具有逾15年的丰富经验。加入富达之前，陈博士是百奥维达中国（BioVeda China）基金的管理合伙人。自2005年以来，陈博士是中国生命科学行业最为活跃的投资者，曾主导对新药研发、药物配给、医疗器械、疫苗、治疗性抗体和工业生物技术等多个领域进行的多项投资。

1997至2005年，陈博士曾担任多家制药和生物技术公司的管理顾问和业务顾问。此外，他曾担任麦肯锡公司和安永公司的管理顾问，并是旧金山湾区生命科学策略咨询公司的创始人之一和管理合伙人。1993至1997年，陈博士在新泽西州先灵葆雅医药公司（Schering-Plough）从事药物开发研制工作。作为研发人员，他还是Vytorin/Zetia（当前该药物已价值数十亿美元）发明团队的一员。

陈博士拥有北京大学理学学士学位以及比利时天主教鲁汶大学有机化学博士学位（最高荣誉奖），并曾在美国麻省理工学院从事博士后工作。他拥有6项已授予的美国发明专利，并是第14和15期安永生物技术报告的作者之一。

问：您如何看待当前中国医疗器械和卫生信息技术服务市场的主要特征？赢家是谁？为什么？

答：将医疗器械和卫生信息技术区分开来很重要。

卫生信息技术从一开始便由中国政府管理。根据中国“十二五”规划公布的当前卫生保健改革计划，中国卫生数据系统正在进行数字化。目前，病历仍多数采用硬拷贝形式，这给医生找到及核查病人记录造成很大麻烦。政府正利用广泛的信息技术平台组织信息。由于多数医院仍由政府所有，数字化的进展相对迅速。私营医院是近年来的发展产物，目前一些国际营运商已涉及该领域。

医疗器械领域目前发展形势可喜。如众多读者所知，所有X光和核磁共振成像设备全球知名厂商（包括通用电气公司、飞利浦公司和西门子公司）进入中国均有逾10年之久。由于在该系统作出大量投资并建立了知名品牌，这些公司一直处于赢家地位。此外，他们还为医生提供培训以及良好的售后支持。

中国公司已找到抢夺小型设备市场（如超声、生化分析、病人监控系统以及较低端的成像系统）的办法。迈瑞（Mindray）在这方面做得很好，宜电（Edan）同样如此。可能在同一领域另外还有两到三家厂商。国内公司在该领域似乎得到更多的支持。此外，本地造产品的质量日渐获得认可。由于人力成本大大低于国外水平，在国内进行生产的公司可以以低于进口产品30%的价格点出售类似的医疗器械产品。

问：医疗器械和卫生信息技术服务市场投资或合作的热点领域是什么？

答：实验室诊断分析仪、血液化学分析和癌症诊断目前是热点。

上述领域的市场总额在10到15亿美元之间。市场以20%的同比增长率继续增长。罗氏（Roche）、雅培（Abbott）及其他公司已进入中国很长时间，且其在该区域作出大量投资。人们了解他们，并将其产品视为最高标准。但是他们的价格也高。至今我们仍未看到大型本土厂商涉猎该领域。国内开发和生产上述领域产品的厂家不到五家。大家都知道他们的质量无法与进口产品的质量相媲美，但较小城市的公立医院通常选择使用他们的产品，尤其是在进行政府资助的一般筛查项目（如乙肝筛查）时更是大量使用该等产品。他们的质量足以完成某些功能。

大型设备市场则难以获得。竞争太激烈，且有些系统一旦装上要5—10年后才需更新。

整形外科领域也很活跃——指人工膝盖和脊柱产品。根据摩根士丹利的研究笔记，整形植入市场正以18%的年均复合增长率强劲增长。截至2015年，该市场预期会成为世界第二大市场。创伤、脊柱和关节产品的低植入率为未来增长预留了很大潜力。可用收入增多、人口老龄化和保险范围扩大是增长的动力。此外，我们还看到了创伤领域的机会。城市建设的持续发展会导致大量意外事故发生。

进口产品的增长不包括人工关节。中国公司能制作钛板和螺丝钉。本土公司将仿造进口产品或找到适当的人制作。这些产品在中国的渗透仍较低。

提示：问题是什么人将为卫生保健的质量买单。中国的卫生保健服务消费者一般不愿意花费大量金钱——在哪儿

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Q&A

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envelope" gifts typically given by the patients' families, but this doesn't necessarily ensure quality of care.

Q: What do you recommend to a public or private U.S. medical device or IT health services company that has great products and technology but does not have the resources or time to grow a local organization in China organically?

A: Partnership. With a really innovative product, you have a lot of room to find a good partner. But the challenge is to find a partner who understands the U.S. culture, how business is conducted. You need someone who can provide the channels necessary to smoothly access the hospitals in China. You need to find someone with mindshare and resources to effectively help protect your IP in China. This is especially important in the medical device sector, given reverse engineering risk. Sooner or later you should have your product made in China to get a better margin based on volume sales. Going in, you need to look at the overall picture and take a five- to 10-year view.

Importantly, you need a partner who can guide you through the distribution process. In China, the distribution is separate for devices and drugs. You need good people to manage your distributors. There are only one or two companies that have licenses to distribute across the country and otherwise the market is highly fragmented with something like 10,000 other regional distributors.

Q: What are the common pitfalls you see in partnering that prospective market entrants to China should anticipate and avoid?

A: You need a team that truly understands China, not only the industry sector, but the culture. Take the time needed to identify the right partner. Chinese partners can show you a bright picture of themselves. Everyone will tell you they know the SFDA minister or even the prime minister. That is common. Do your due diligence, including looking into the reputation of the company. Find the people who have operated in China for some time and not people who have just arrived or returned to China. Someone may be in China, but lived and studied in the U.S. for a while. They could end up giving you the opposite picture of what's actually the case. You might have checked many of the right boxes, but a failure to address regulatory or corruption risk properly can bring down your business. If you are dealing with a returnee who previously left China to seek education or employment in the U.S. or Europe, make sure they have been back in China for at least three years.

Q: What do you see as the key trends for the med device and IT health services markets in the next 12 to 18 months?

A: The medical device sector is all about innovation. The government is putting a lot of money into the sector to help returnees and local companies who are making innovative products. But you can think of it as "conservative innovation." Very few, if any, products that originate in China can be described as innovative in the full sense as yet. But in certain fields, such as surgical devices, you will see "import replacements." China is now making its own stents. Expect that your product will be copied, and proactively manage that by partnering with someone local if you want to be in a good position to capture the market share in China. Also, find a partner who can help you get into developing countries such as Greece and Turkey.

Q: What steps should foreign companies take in light of health care reform measures?

A: The reforms raise numerous issues. Since many foreign companies are trying to expand in the China pharma/health care services markets, one result is that over time, the government is going to ask everyone to lower their prices in China.

The short of all this is that in practice, companies are going to be allowed only a certain percentage of profit margin, meaning that you have to figure out a way to deal with this in your business model. Price controls will be severe and, for some, it may not provide enough profit margin to make it worth selling their product. Most multinationals are trying to find a way to manufacture their products in China by acquiring a local company, and leveraging volume manufacturing and sales as quickly as possible.

Q: Do you think the regulatory environment in China currently is helping or hindering collaboration of medical tech and IT health services between U.S. and Chinese companies?

A: I think the system is helping collaboration for some categories but hindering it for others. For instance, some Chinese companies have cornered the stent sector. It's going to be difficult for foreign companies to get approval for a new stent. Chinese-made stents are good enough. Or the SFDA will raise the standard, maybe by asking a company to run a clinical trial on 3,000 patients.

The way the government is supporting collaboration is through "joint ventures." Products that come out of a JV inside China will be in favor over imported products of the same category. Companies should try to think how to leverage China's current investment in innovation to develop their products to accomplish or accelerate what they are doing outside China. There is a financial benefit, and through the process the foreign company will learn about China. It may lead to another joint venture. If a company tries to do distribution on its own, you are asking for trouble and will never learn how a product will be sold in China.

Q: Finally, are there any collaboration trends you would identify as representative?

A: Joint ventures remain relevant. Medtronic formed a joint venture with a local company, Shandong Weigao, in the orthopedic sector. Medtronic holds 51 percent of the JV while Weigao holds 49 percent. I understand it's done pretty well. Foreign companies with the right resources can effectively manage majority-owned JVs, but you need the right people locally to own the project's success and make it work. We see both large and small foreign device companies wanting to figure out the right way to enter the market in China.

问与答

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不是这样呢？以进口产品一半的价格便能买到同等质量的本土造器械。中国的手术费比美国低得多，但存在隐性花费。有些医生仍在收取病人家属通常赠送的“红包”礼物，但这不一定能保证获得优质服务。

问：美国有些上市或未上市的医疗器械或卫生信息技术公司拥有很棒的产品和技术，但没有资源或时间在中国“有机地”培养当地机构。你对此类公司有何建议？

答：找合作伙伴。只要拥有真正具有创新性的产品，你完全有机会找到不错的合作伙伴。但问题是如何找到了解美国文化及商业运作的合作伙伴。你需要能为顺利打入中国医院提供必要渠道的人。你需要找到既有口碑、又有资源来有效地帮你在中国保护知识产权的人。因为存在反向工程风险，这在医疗器械行业尤为重要。你迟早要在中国制造产品，以便通过大批量销售获得更高的利润率。要进入市场，你需要了解全局，并做5至10年的打算。

重要的是，你需要能帮你解决经销问题的合作伙伴。在中国，器械和药品的经销是分开的。你需要适当的人来管理经销商。只有一两家公司有全国经销许可，而存在大约10,000家其他地区经销商的市场又高度分化。

问：对于有望进军中国市场的公司而言，在建立合作伙伴关系方面他们应预见并避免哪些常见并易犯的错误？

答：你需要一个真正了解中国的团队，不仅仅是有关行业领域，还有文化。花必要的时间确定适当的合作伙伴。中国合作伙伴会向你展示他们自己光鲜的一面。他们都会告诉你说他们认识国家食品药品监督管理局局长，甚至认识总理。这很常见。你自己要做尽职调查，包括调查有关公司的信誉。找已在中国经营一段时间的人，而不是刚来到或刚回到中国的人。有些人可能目前在中国，但曾在美国生活、学习过。他们可能会告诉你与事实截然相反的情况。你可能做了许多正确的选择，但你的业务可能会因处理监管或腐败风险不当遭殃。如果同曾在美国或欧洲求学或求职的归国人员打交道，要确定他们已回国至少三年。

问：您认为医疗器械和卫生信息技术服务市场在以后12-18个月的主要趋势是什么？

答：创新是医疗器械行业的关键。政府将在该行业投入大量资金来帮助制造创新性产品的归国人员和当地公司。但你可以将此视为“保守的创新”。很少有源于中国的产品可被称为真正意义上的创新性产品。但在某些领域（如手术器械），你会看到“进口替代品”。中国目前正在制造国产血管支架。要预想到你的产品会被复制，如果你想在中国市场份额争夺战中占据有利地位，一定要利用当地的合作伙伴积极控制这种情况。另外，要找可帮你进入希腊和土耳其等发展中国家的合作伙伴。

问：外国公司应针对卫生保健改革办法采取哪些措施？

答：改革会引起若干问题。因为许多外国公司正试图在中国医药/卫生保健市场上扩张，一种结果是随时间流逝政府将要求所有人降低在中国的价格。

所有这些措施的缺点是公司实际上只可获得一定百分比的利润率，这意味着你一定要在自己的业务模式内找到处理此事的方法。价格控制会很严厉，并且对某些公司来说，获得的利润率可能让他们感觉卖东西不合算。多数跨国公司正试图找到办法尽快通过收购本地公司及利用批量生产和销售优势来在中国生产产品。

问：你认为中国的监管环境目前是在促进还是在阻挠中、美公司之间的医疗技术和卫生信息技术服务合作？

答：我认为有关制度对某些产品合作有促进作用，但对其他产品合作有阻挠作用。例如，有些中国公司已经垄断了血管支架行业。新型血管支架会难以获得批准。中国国产支架已经够好了。监管机关也可能会通过要求公司在3,000名患者身上进行临床试验等来提高标准。

政府支持合作的方法是通过“合营”。由中国境内的合营企业生产的产品将会比同一类别的进口产品更受欢迎。公司应努力思考如何影响中国在创新方面的投资，从而开发自己的产品来实现或促进他们在中国以外的目标。这会产生经济利益，并且通过这个过程，外国公司将会了解中国。这会导致设立另一家合营公司。如果试图自己做经销，你是自找麻烦，也永远不会学会在中国销售产品的方法。

问：最后，是否存在您认为具有代表性的趋势？

答：合营公司仍具有重要意义。美国美敦力和一家当地公司山东威高一起设立了一家属于整形外科领域的合营公司。美敦力持有合营公司的51%，威高持有49%。据我了解他们搞得相当不错。拥有适当资源的外国公司可有效地管理由其拥有多数股权的合营公司，但是，要让项目成功并富有成效，你需要适当的当地人帮忙。我们看到大大小小的外国医疗器械公司都想找到进军中国市场的正确途径。

Implications of the Leahy-Smith America Invents Act for Chinese Life Science Companies

By Peng Chen and Kun Wang

The Leahy-Smith America Invents Act (AIA) was signed into law by President Barack Obama on September 16, 2011. Major changes in the AIA related to pre-issuance proceedings include: 1) switching to a mostly first-to-file system; 2) simplifying the prior art statutory sections; and 3) replacing interference proceedings with limited derivation proceedings. The AIA also brings numerous significant changes for post-grant proceedings, including the new post-grant review proceeding that allows many validity and enforcement issues, traditionally reserved for the courts, to be addressed in the United States Patent and Trademark Office (USPTO), and the new supplemental examination proceeding that allows a patent owner to address a potential inequitable conduct issue in the USPTO before starting litigation.

First to File

The AIA transforms the United States from a "first-to-invent" jurisdiction to one where the right to a patent is given to the party that is "first-to-file."[1] Going forward, the inventor with the earliest-filed application is now the one entitled to claim the patent. The change in the law serves to harmonize the United States' patent system with that of every other major jurisdiction throughout the world.

Grace Period and Prior Art

In addition to changing the U.S. patent system from a first-to-invent to a first-to-file system, the AIA significantly alters the nature of the prior art grace period. Under the previous statute, inventors enjoyed robust protection against disclosures, public use or sales that occurred within one year of the filing date, regardless of who was responsible for the disclosure. Under the new statutory system, any printed publication, public use, sale or availability to the public even a day before the effective filing date of the claimed invention can be novelty-defeating. The AIA keeps a more limited type of grace period by amending § 102 to except from § 102(a)(1) only disclosure made within one year prior to the effective filing date by the inventor, co-inventor or any third party who obtained the disclosed subject matter either directly or indirectly from an inventor.[2] The AIA removes certain patents and applications as prior art under § 102(a)(2), where the subject matter was developed under a joint research agreement.[3] The AIA also eliminates patents and applications as prior art where the disclosed subject matter and claimed inventions were commonly owned or subjected to common assignment by the time of the effective filing date.[4]

THE AIA TRANSFORMS THE UNITED STATES FROM A "FIRST-TO-INVENT" JURISDICTION TO ONE WHERE THE RIGHT TO A PATENT IS GIVEN TO THE PARTY THAT IS "FIRST-TO-FILE." GOING FORWARD, THE INVENTOR WITH THE EARLIEST-FILED APPLICATION IS NOW THE ONE ENTITLED TO CLAIM THE PATENT.

The AIA expands the scope of materials to be considered as prior art. For example, the "on sale" and "in public use" activities are no longer limited to the United States under the AIA, but are global issues. The AIA also removes the distinction between U.S. applications and foreign, priority applications as prior art, also known as the Hilmer doctrine. Further, under the AIA, third parties will now be able to play a larger role in prosecution because the AIA allows for greater pre-issuance input. Under the current law, third parties can only submit prior art in applications before publication. The AIA permits third parties to submit prior art after publication or the first rejection, but before a notice of allowance.

Derivation Proceedings

The AIA also creates a new "derivation" proceeding to replace the interference proceeding under the current law. Derivation proceedings are essentially proceedings to determine whether the inventor named in an earlier-filed application derived the claimed invention from the inventor of an application filed later. A peitition to institute a derivation proceeding may be filed by an applicant within one year after publication of a claim to an invention "that is the same or substantially the same as the earlier application's claim . . . ." The newly formed Patent Trial and Appeal Board (PTAB), which is staffed by administrative patent judges and replaces the current Board of Patent Appeals and Interferences, will adjudicate such proceedings.

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美国专利法改革法案对中国生命科学公司的影响

作者：陈朋博士和王堃博士

《美国专利法改革法案》（“专利法改革法案”）于2011年9月16日经美国总统奥巴马正式签署为法律。专利法改革法案关于专利授予前程序的重大转变包括：(1) 大多转为先申请先得制度；(2) 简化了现有技术的法定章节；及(3) 以有限的申请人调查程序替代干涉程序。专利法改革法案也带来授予后程序的多项重大转变，包括新的专利授予后审核程序，该程序容许很多传统上保留由法院处理的有效性和强制执行问题转移到专利商标局解决，而新的补充审查程序容许专利所有人在展开诉讼前于专利商标局解决潜在的不公平行为问题。

先申请先得

专利法改革法案让美国从一个“先发明先得”的法域，转变成了专利权给予“先申请”[1]的一方的法域。现在，最先提交申请的发明者就是有权要求专利权的人。此法律转变使美国的专利制度与世界上其他各个主要法域的专利制度一致。

宽限期及现有技术

除了将美国专利制度从先发明先得改为先申请先得以外，专利法改革法案显著地改变了现有技术宽限期的性质。根据以前的成文法，不论谁对披露负责，发明者对在申请提交日之前一年内发生的披露、公开使用或出售享有有力的保护。根据新的法定制度，就算在有效申请提交日前一天发生的任何印刷出版、公开使用、出售或向公众提供

专利法改革法案让美国从一个“先发明先得”的法域，转变成了专利权给予“先申请”的一方的法域。现在，最先提交申请的发明者就是有权要求专利权的人。

也会使所要求的发明丧失新颖性。专利法改革法案修订了第102条，以保持一种更为有限的宽限期，经修订后，第102(a)(1)条的例外情况仅为发明者、共同发明者、或直接或间接从发明者处获得披露标的之任何第三方于有效申请提交日前一年内做出的披露。[2] 当某些有关专利和申请的标的为根据联合研究协议开发的成果时，专利法改革法案不再将其视为第102(a)(2)条项下的现有技术。[3] 如果有关的专利和申请所披露的标的和要求的专利在有效申请提交日之前是共有的或经过共同转让的，专利法改革法案也不再将其视为现有技术。[4]

专利法改革法案扩大了被视为现有技术的资料范围。例如，根据专利法改革法案，“在售”及“公开使用”活动不再限于美国境内，而是全球性的问题。专利法改革法案取消了美国优先权申请与外国优先权申请之间作为现有技术的区别，或称为Hilmer原则。此外，根据专利法改革法案，第三方现在能够在审查方面担当更重要的角色，原因是专利法改革法案允许第三方在授予专利前提供现有技术。根据目前的法律，第三方仅可于公布前的申请中提供现有技术，而专利法改革法案允许第三方在公布或首次拒绝后提交现有技术，但须在核准通知出具前提供。

申请人调查程序

专利法改革法案创制了一种新型的“申请人调查”程序以替代现有法律下的干涉程序。申请人调查程序的主要目的是确定先提交的申请中的发明人是否是从后提交的申请中发明人处取得所要求的发明的。申请人调查程序应由申请人在对一项发明提出的权力要求公布后的一年内提起，“且其与先提交的申请的权力要求一样或基本一样…”。新组成的专利审理和上诉委员会代替现有专利上诉和干涉委员会，由行政专利法官组成，并将裁定该等程序。

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Leahy-Smith

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Post-Grant Proceedings

The AIA brings numerous significant changes for post-grant proceedings. One of the fundamental changes is that the AIA allows many validity and enforcement issues, traditionally reserved for the courts, to be addressed in the USPTO. After its effective date, a third-party petitioner can challenge validity of issued patents on broad grounds, including invalidity issues under 35 U.S.C. § 101 and § 112, in post-grant review. This new post-grant review proceeding is a significant change from the current reexamination practice because, for the first time, a third-party petitioner can raise issues beyond the issues allowed in the current reexamination, which are limited to the invalidity issues based on prior art patents and printed publications. This is also the first time where a third-party petitioner can raise prior art and § 112 issues in the same proceeding in the USPTO.

Compared to litigation in the federal courts, the post-grant review proceedings in the USPTO offer several advantages. First, the post-grant review is conducted by the PTAB, which should be well-qualified to understand and decide on complex and patent law issues. In addition, the patentability issues are determined according to a lower evidentiary standard—a preponderance of evidence standard, not the more demanding "clear and convincing" standard used in civil litigation. Further, with a more limited discovery procedure, the post-grant review can be conducted at a lower cost than civil litigation.

Another fundamental change is that a third-party petitioner can challenge validity of patents from applications filed before November 29, 1999, in *inter partes* review. Currently, the validity of these patents can only be challenged in *ex parte* reexamination in the USPTO, wherein the third-party requester only has limited participation. In contrast, a third-party petitioner has full participation in an *inter partes* review. For some patents, e.g., biotech and pharmaceutical patents, the later patent term is often more lucrative. After the effective date in September 2012, these patents will be open to *inter partes* review.

Still another fundamental change is that a patent owner can address a potential inequitable conduct issue in the USPTO before starting litigation in the new supplemental examination proceeding. Since inequitable conduct is often an important issue in some patent litigation, e.g., pharmaceutical patent litigation and ANDA litigation, the new supplemental examination proceeding gives a patent owner an opportunity to address this issue proactively in the USPTO. If conducted successfully, the patent owner can prevent a defendant from raising the inequitable conduct issue in future civil litigation.

Implications for Chinese Life Science Companies

The AIA begins a new era of patent practice in the United States and has implications for Chinese life science companies seeking protection of their intellectual property and conducting business here. Companies will need to reevaluate their patent application filing strategies and their policies regarding public disclosure of their inventions in view of the shift to first-to-file and the changes to what is considered prior art.

Under the AIA, an inventor's early filing date is important because any disclosure by a third party prior to the inventor's filing date will normally be seen as prior art that can negate patentability. There are two major exceptions to this general rule: a third-party disclosure within one year of the applicant's filing date does not count as prior art if either (1) the inventor had already disclosed the invention prior to the third-party disclosure or (2) the third-party disclosure was somehow derived from the inventor.[5]

THE AIA BEGINS A NEW ERA OF PATENT PRACTICE IN THE UNITED STATES AND HAS IMPLICATIONS FOR CHINESE LIFE SCIENCE COMPANIES SEEKING PROTECTION OF THEIR INTELLECTUAL PROPERTY AND CONDUCTING BUSINESS HERE.

Because under the AIA prior art becomes a global issue, commercial and research activities outside the United States have to be coordinated with the filing of U.S. applications. As a result, inventors and companies should ensure that they have filed patent applications before drumming up business, even confidentially, for their inventions anywhere in the world.

It would also be a good strategy to create joint inventorships in order to avoid prior art issues. This may be accomplished by signing joint research agreements between companies entering into a collaboration. But to benefit from any collaborative efforts, proposed § 102(c) requires that (1) the joint research agreement be in force by the effective filing date; (2) the claimed invention be a result of the joint research efforts; and (3) the application disclose the parties to the joint research agreement.

The utility of U.S. provisional applications is diminished by the removal of the

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专利法改革法案

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授予后程序

专利法改革法案对授予后程序进行很多重大改变。其中一个根本的改变是专利法改革法案允许很多有效性和执行性问题由专利商标局解决，传统上这些问题都是由法院解决的。本法案生效之后，第三方申请人可以从更广的意义上质疑已发出的专利的有效性，包括在授权后审查美国专利侵权法规第35章下第101和102条相关的问题。该等新的授权后的审查程序与目前的复核程序有重大不同，因为第三方申请人首次可以在现有的复核程序允许的范围外提出问题，而该现有范围仅限于现有技术专利和印刷出版的有效性问题。这也是第三方申请人首次可以就在同样的程序中在专利商标局提起关于现有技术和第112条的问题。

与联邦法院的诉讼相比，专利商标局授予后的审查程序也带来很多好处。首先，授权后审查是由专利诉讼和上诉委员会执行的，其应有能力理解和决定复杂的专利法律问题。还有，可进行专利登记的问题根据更低的证据标准决定，即优势证据标准，而不是更严格的民事诉讼中使用的“清晰并令人信服的”标准。而且，随着更加受限的调查程序，授权后审查可以按比民事诉讼更低的成本进行。

另外一个重大变化是第三方申请人可以根据多方审查质疑申请日在1999年11月29日前的专利的有效性。目前，该等专利的有效性只能通过专利商标局的多方复核才能进行挑战，而且第三方请求人只有有限的参与。相比较而言，第三方申请人可以全面参与多方审核。对于某些专利，比如，生物科技和医药专利，较后的专利期限通常更加有利可图。在2012年9月生效日之后，该等专利将可以进行多方审核。

另外一个根本的变化是专利所有人可在诉讼开始前新的补充审查程序中，在专利商标局处理潜在不公平行为的问题。因为不公平行为经常是一些专利诉讼的重大问题，如医药专利诉讼和新药申报简略程序的诉讼，新的补充审核程序给了专利所有人一个机会主动在专利商标局解决这个问题。如果处理成功，专利所有人可以阻止被告人在未来的民事诉讼中提起不公平行为问题。

对中国生命科学公司的影响

专利法改革法案开启了美国专利实务的新时代，并对在美国寻求知识产权保护和开展业务的中国公司具有一定影响。由于向先申请先得机制的转变以及对现有技术定义的变更，公司需要重新评估其专利申请提交战略和与公开披露发明有关的政策。

根据专利法改革法案，发明人的提交申请日期务必要早，因为第三方在发明人申请提交日之前进行的披露通常会被视为现有技术，而现有技术会导致有关专利丧失可专利性。此项一般规则主要有两种例外情况，即在以下两种情况下，第三方在申请人申请提交

专利法改革法案开启了美国专利实务的新时代，并对在美国寻求知识产权保护和开展业务的中国公司具有一定影响。

日之前一年内做出的披露不算现有技术：(1) 发明人在第三方披露之前已经披露了发明；或 (2) 第三方的披露内容是以某种方式从发明人处取得的。[5]

因为根据专利法改革法案，现有技术已成为全球问题，美国境外的商务和研究活动必须与美国专利申请的提交相协调。因此，发明人和公司应确保在世界无论任何地方为其发明招徕生意之前提交专利申请。

为避免现有技术问题，建立共同发明人关系也是一个良策。为此，达成合作关系的公司可签署共同研究协议。但要想从合作工作中受益，建议的第102 (c) 条要求：(1) 共同研究协议应在有效申请提交日期之前有效；(2) 所主张的发明是合作研究工作的成果；以及 (3) 申请书要披露合作研究协议的当事人。

因为美国临时申请和外国优先权证明文件之间做为现有技术的区别已不存在，美国临时申请的效用降低了。另一方面，如果使用得当，对发明人披露现有技术的除外规定可满足现金紧张的

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distinction between U.S. provisional applications and foreign priority documents as prior art. On the other hand, the exceptions of disclosure by the inventor as prior art may serve the need for companies that are cash-strapped, when used properly, by replacing the need for filing a U.S. provisional application to establish a priority date. Under the AIA, self-disclosure offers similar benefits to that of a provisional application in that it is cheap, with few formalities and provides an additional year of delay. The disclosure allows an applicant to buy an additional year of delay with few capital expenditures and without losing patent term, but instead merely shifts the term forward in time.

However, caution must be taken when using the pre-filing disclosure strategy. Most importantly, a pre-filing disclosure would substantially negate the potential for non-U.S. patent rights because most other countries have a more absolute rule that pre-filing disclosures negate patentability. Further, efforts are needed to make sure that such disclosure is sufficient for its priority purposes.

After the AIA, numerous procedures are or will be available for challenging or addressing the validity and enforceability of issued patents. Selection of a particular procedure depends on many factors such as availability, issues to be raised, desired level of participation, estoppel concern and cost consideration. Currently, only *ex parte* reexamination and *inter partes* reexamination are available for challenging or addressing the validity of issued patents. *Inter partes* review, supplemental examination and transitional post-grant review for business method patents will become available in September 2012. For most patents, post-grant review will not become available until March 2013 or later.

Ex parte reexamination and *inter partes* reexamination can only be raised based on prior art patents or printed publications, including anticipation, obviousness and obviousness double patenting issues. *Inter partes* review can only be raised based on prior art patents or printed publications, but obviousness double patenting issues cannot be raised. Post-grant review can be based on any grounds under 35 U.S.C. 282 § (2) and (3), including invalidity issues under 35 U.S.C. § 101, 102, 103, 112 and 251 (for reissue patent). However, obviousness-type double patenting and enforceability issues cannot be raised in a post-grant review. A patent owner may request supplemental examination to consider, reconsider or correct information believed to be relevant to the patent, which is not limited to patents and printed publications.

CAUTION MUST BE TAKEN WHEN USING THE PRE-FILING DISCLOSURE STRATEGY. MOST IMPORTANTLY, A PRE-FILING DISCLOSURE WOULD SUBSTANTIALLY NEGATE THE POTENTIAL FOR NON-U.S. PATENT RIGHTS BECAUSE MOST OTHER COUNTRIES HAVE A MORE ABSOLUTE RULE THAT PRE-FILING DISCLOSURES NEGATE PATENTABILITY.

Needless to say, a third-party challenger only has limited participation in *ex parte* reexamination, which is often perceived to be less effective than other *inter partes* proceedings from the third party's vantage. However, there are still reasons for considering *ex parte* reexamination even when other *inter partes* proceedings are available. For example, once the *inter partes* reexamination is replaced by *inter partes* review in September 2012, *ex parte* reexamination will be the only proceeding to raise an obviousness double patenting issue in the USPTO. In addition, *ex parte* reexamination carries no formal estoppel effect and usually costs less than the other *inter partes* proceedings.

The various *inter partes* proceedings, including *inter partes* reexamination, *inter partes* review, post-grant review and transitional post-grant review for business method patents, are generally regarded as more effective in challenging the validity of issued patents because a third-party challenger has full participation in these proceedings. On the other hand, these *inter partes* proceedings carry formal estoppel effect, i.e., the third party is estopped from raising or maintaining invalidity challenges on any ground that was raised or reasonably could have been raised in the USPTO and civil proceedings.[6] In the end, selection of a particular procedure must be based on multiple factors, as discussed above, as well as one's objective in the post-grant proceeding and its potential impact on other related civil proceedings, such as litigation in courts and ITC proceedings.

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[1] § 102(a)(1).

[2] § 102(b)(1)(A).

[3] § 102(b)(2)(C).

[4] *Id.*

[5] § 102(b)(1)(B).

[6] For *inter partes* reexamination, the third party is estopped from raising or maintaining invalidity challenges on any ground that was raised or could have been raised.

专利法改革法案

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公司的需要，使这些公司无需再为确立优先日期而提交美国临时申请。根据专利法改革法案，自我披露的好处与临时申请差不多，因为自我披露手续简便、费用低廉，同时允许额外延期一年。这种披露使申请人只需支付少许费用便可再延期一年，同时不会丧失专利期限，只是将期限的时间提前。

但是，在使用申请前披露策略时必须要小心。最重要的是，申请前披露会实际排除在美国境外获得专利权的可能，因为多数其他国家有对于提交申请前披露会使申请丧失可专利性的更为绝对地规定。另外，需要努力确保该等披露足可获得优先权。

专利法改革法案实施之后，大量现有或将来制定的程序可用于质疑或处理已授专利的有效性或可执行性问题。具体程序的选择取决于许多因素，比如可利用性、拟提出的问题、希望的参与程度、禁止反言方面的顾虑以及费用考虑等。 目前，只有单方复审和双方复审可用来质疑或处理已授专利的有效性问题。从2012年9月开始，可对商业方法专利采用双方审查、补充审查和过渡授予后审查。对于多数专利而言，只有到2013年3月或更晚时候才可采用授予后审查。

单方复审和双方复审仅可以根据先有技术专利和印本出版物提出，包括预见性、显而易见性和显而易见重复专利问题。双方审查仅可以根据先有技术专利或者印本出版物提出，但是不能根据显而易见重复专利问题提出。授予后审查可以基于《美国法典》第35篇第282章第（2）和第（3）条中的任何依据进行，包括《美国法典》第35篇第101条、第102条、第103条、第112条和第251条项下的专利无效问题（为了重新授予专利）。但是，在授予后审查中不能提出显而易见类型的重复专利和可执行性问题。专利所有人可要求进行补充审查，从而考虑、重新审议或者更正认为与专利有关的信息，其不局限于专利和印本出版物。

在使用申请前披露策略时必须要小心。最重要的是，申请前披露会实际排除在美国境外获得专利权的可能，因为多数其他国家更为绝对地规定提交申请前披露会使申请丧失可专利性。

毫无疑问，第三方质疑者参与单方复审的程度是有限的，从第三方的角度来看，经常认为单方复审的有效性不如其他双方程序。但是，即使可以采用其他双方程序，仍有理由考虑单方复审。 例如，在2012年9月一旦双方复审被双方审查所取代，单方复审将成为在专利商标局提出显而易见重复专利问题的唯一程序。此外，单方复审不具有正式的禁止反言效用，而且通常情况下，费用比其他双方程序的费用低。

各种双方程序，包括适用于商业方法专利的双方复审、双方审查、授予后审查以及过渡授权后的审查，通常被视为是质疑已授予专利有效性的更有效方法，因为第三方质疑者可以全面参与该等程序。另一方面，该等双方程序具有正式的禁止反言效用，例如：第三方被禁止以在专利商标局和民事程序中提起的或本应合理提起的任何理由提出或维持无效质疑。[6] 最终，具体程序的选择必须基于以上讨论的多种因素，以及基于在授予后程序中某人的目标和其对其他有关民事程序的潜在影响（例如在法院和美国国际贸易委员会程序中的诉讼）。

[1] 第102(a)(1)条。
[2] 第102(b)(1)(A)条。
[3] 第102(b)(2)(C)条。
[4] 同上。
[5] 第102(b)(1)(B)条。
[6] 对于双方复审，第三方被禁止以提起的或本应提起的任何理由提出或维持无效质疑。

Frequent Issues Arising in Acquisitions of China Life Sciences Targets

By Thomas Chou, Gordon Milner and Eric Dickinson

China is the world's third-largest pharmaceuticals market in terms of revenue. In 2011, it is projected to grow 27% to more than $50 billion. By 2014, it will have surpassed $100 billion. Significant opportunities exist for players in this industry, as the landscape remains heavily fragmented, with the largest competitors occupying only 3-6% of the market. Unsurprisingly, China now ranks as the most attractive M&A destination in Asia for foreign life sciences companies, and making such investments has turned out to be a winning strategy for many.

Foreign life sciences companies have become more comfortable acquiring specialized distributors and R&D firms involved in the creation of innovative therapeutics and devices.

Notwithstanding the increasing focus on China life sciences M&A, foreign firms must tread carefully when doing deals in this industry. A thoughtful due diligence exercise is critical in order to effectively manage risk, and the value of assessing a potential target cannot be overstated. Focusing on priority areas and formulating a risk analysis will directly translate into the ability to identify and intelligently address issues with respect to management, operations and internal controls.

Below are some key points that should be considered.

Beware of Anti-Bribery and Anti-Corruption Laws

Promotional payments (commonly known as "bribes") that may violate the U.S. Foreign Corrupt Practices Act (FCPA), Chinese anti-corruption laws and the UK Bribery Act 2010 are commonplace in the Chinese health care ecosystem.

The good news is that the Chinese government is aware of the problem and has stepped up its own efforts to stamp out such corruption. It is particularly focused on abating corruption within state-owned companies, which include most hospitals and health care facilities. In addition, the government is cracking down on "pay-to-play"-type corruption, including overseas. Earlier this year, the Standing Committee of the National People's Congress passed the Eighth Amendment to the Criminal Law of the PRC. The amendment, which went into effect on May 1, 2011, makes it a crime to make payments to non-PRC government officials and to officials of international public organizations for any illegitimate commercial benefit.

THE EXPLOSIVE GROWTH OF CHINA'S LIFE SCIENCES INDUSTRY IS EXPECTED TO CONTINUE WELL INTO THE FUTURE. HOWEVER, THE DRIVE TO CLOSE TRANSACTIONS MAY LEAD STRATEGIC INVESTORS TO ACCEPT RISKS THAT ARE NOT FULLY PERCEIVED OR PROPERLY UNDERSTOOD AT THE TIME OF DEAL EXECUTION.

The newly enacted UK Bribery Act came into effect in July 2011, dramatically raising the bar on international anti-corruption enforcement. Unlike the U.S. FCPA, the Bribery Act imposes *strict liability* on companies that fail to prevent their employees and people "associated" with them from engaging in bribery—i.e., liability arises under the Act regardless of the intent of the defendant. As an even more significant departure from the FCPA, criminal liability under the Bribery Act is not limited to those who bribe public officials; rather it extends to bribery of any party, including bribes to private sector employees.

It is imperative for management of any foreign firm seeking to conduct M&A activity in China to be adequately advised on the laws of each of the U.S., UK and the PRC when undertaking due diligence for an acquisition. Furthermore, prior to closing, a company should require the provision of appropriate representations, warranties, indemnities and covenants designed to assist in the identification, mitigation and allocation of any potential anti-corruption liabilities.

Intellectual Property Issues

Intellectual property matters are generally of fundamental importance to any company in the life sciences industry and China is no exception to this rule. Since acceding to the WTO in 2001, China has taken great strides to bring its intellectual property laws into line with those prevalent throughout the rest of the world. In particular, PRC law recognizes and protects all of the major categories of intellectual property rights, including patents, trademarks, and copyrights.

Difficulties with enforcement (particularly against Chinese parties away from the major cities) have lead to a general perception that protecting any form of intellectual property in China is difficult. It would, however, be a mistake to be overly influenced by this perception.

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收购中国的生命科学公司目标所经常引起的问题

作者：周至恒, Gordon Milner和丁睿克

中国是以销售收入计算的世界第三大医药市场。在2011年，该市场预计增长27%至超过500亿美元。到了2014年，其价值将超过1,000亿美元。由于整个行业仍然被大幅分割，主要竞争者仅占市场的3-6%，业内人士拥有很多重要的机会。不令人感到意外的是，现在对外国生命科学公司来说，中国是亚洲区内最具吸引力的并购目的地而进行该等投资已经成为很多公司的优胜策略。

外国公司在收购从事创造创新疗法及装置的专有分销商和研发公司方面开始越来越放开手脚。

尽管对并购中国生命科学公司的关注日益增加，外国公司在进行此行业的交易时必须加倍小心。就管理风险而言，进行缜密的尽职调查是有效风险管理的关键，且对潜在目标的评估至关重要。对于优先领域的关注及进行风险分析将直接转化为发现、并明智地解决关于管理、运营及内部控制方面问题的能力。

以下是应该考虑的一些重点问题：

注意反贿赂及反腐败法律

在中国的保健生态系统司空见惯的奖励性质付款（统称 “贿赂”）可能会违反美国的《海外腐败行为法》、中国的反腐败法律及英国的2010年《反贿赂法案》。

中国政府已经察觉问题所在并已进一步采取行动以扑灭该腐败行为，特别针对包括大部分医院及保健场所的国有公司的贪污情况。此外，政府正打击 包括海外的“付款换取参与”一类的贪污情况。今年较早前，全国人大常务委员会通过《中华人民共和国刑法》第八修订案。该修订案于2011年5月1日生效， 因此，就任何非法的商业利益向外国政府官员及国际公共组织的官员付款属于犯罪。

> 中国的生命科学行业的爆炸性增长预期在将来还会有良好的持续势头。不过，由于受完成交易所驱，策略性投资者面临着接受在执行交易时没有完全察觉或适当理解的风险。

新颁布的英国《反贿赂法案》在2011年7月生效，显著地提高了对国际反腐败实施的标准。不像美国的《海外腐败行为法》，《反贿赂法案》对未能防止其雇员及与之“关联”的人进行贿赂的公司加诸严格责任—即根据法案引起责任，而不论被告人的意图。与《海外腐败行为法》之间更重大的偏离是《反贿赂法案》下的刑事责任不限于贿赂公职人员；该责任扩大至任何一方的贿赂，包括贿赂私人行业的雇员。

在进行收购的尽职调查时，最重要的是任何寻求在中国境内进行并购活动的外国公司的管理者须充分听取相关的美国、英国及中国的法律意见。此外，在交割前，一家公司应要求作出为协助认定、减轻及分配任何潜在的反贪污责任之适当陈述、保证、赔偿和公约的规定。

知识产权问题

通常知识产权问题对生命科学领域的任何公司而言都是至关重要的，而中国在这一准则中也不例外。自2001年加入世贸组织以来，中国已经加大步伐使其知识产权法与世界其他地区适用的知识产权法保持一致。特别是中国法律认可并保护知识产权的所有主要类别，包括专利、商标和版权。

执法困难（尤其是针对非主要城市的中方）已经导致了一种在中国保护任何形式知识产权均十分困难的观念。但是过度受这种观念影响是错误的。知识产权经常性的在中国法院或通过政府管理行为成功执行。而且想

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Frequent Issues

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Intellectual property rights are successfully enforced in the Chinese courts and by government administrative actions on a regular basis, and it is essential that a foreign company looking to acquire a Chinese life sciences company undertake thorough due diligence on the intellectual property used by the target business in order to assess whether any unauthorized use is being made of third-party intellectual property. In particular it is highly recommended that the acquiring company engage in freedom to operate and non-infringement analyses of the target's key processes and products.

When it comes to the target's own intellectual property assets, it is important to understand that in China, the enforcement of registered IP rights (such as patents and trademarks) is generally much easier than unregistered rights such as copyrights and trade secrets. To this end, it will be important to conduct a thorough review of the target's portfolio of registered rights to assess gaps in protection, oppositions and chain of title defects, etc.

For the same reason, a target that relies wholly or materially on trade secrets protection of its core technologies is likely to present a greater risk in China than it would in other jurisdictions. That being said, it is inevitable that many life sciences companies (particularly biotech companies and manufacturing businesses) will depend heavily on "know-how" contained within the business. When acquiring such targets by way of an asset transfer, it is important to agree to practical arrangements for the transfer of "know-how," and not merely rely upon a bare legal assignment in the acquisition agreement. A prudent acquirer may want to consider using the handover of "know-how" as a condition to close the acquisition and/or using it as a trigger for a tranche of the purchase price. In general, the agreement should provide for:

- The handover of relevant physical documentation (including its creation or collation if the existing documentation is not adequate).
- Appropriate training and consultation mechanisms to ensure an exhaustive knowledge transfer to the purchaser.
- Confidentiality, disclosure and use restrictions upon the vendor (these are important as, unlike most other assets, the transfer of know-how is not a "zero-sum" game because the act of disclosure to the acquirer does not in itself extinguish the existence of the know-how in the hands of the vendor).

Regulatory Due Diligence

Depending upon the nature of the target's business, it may be required to hold and maintain several different government approvals and permits in order to operate in China, both in connection with the scope of its business license and on a per-product basis. The purchaser will need to conduct regulatory due diligence to assess the target's compliance with several layers of regulatory complexity, including:

- **Pharmaceutical Product Import Approval:** all medicines imported for distribution in China require an import approval from the State Food and Drug Administration (SFDA). This is also true for medical devices. These approvals are granted on a per-product basis and will typically be in the name of the offshore manufacturer.
- **Pharmaceutical Product Approval:** all medicines manufactured domestically for distribution in China will require product approval from the SFDA. This is also granted on a per-product basis but must be in the name of the domestic manufacturer (notwithstanding that the product may use APIs and other compounds licensed or purchased from an offshore party).
- **Pharmaceutical Manufacturing Permit:** domestic manufacturers of pharmaceutical products must hold this permit.
- **Good Manufacturing Practices (GMP) Certification:** domestic manufacturers of pharmaceutical products must hold this certification.

Anti-Monopoly Law Issues

In August 2007, the Standing Committee of the National People's Congress (NPC) adopted the country's first significant and comprehensive anti-monopoly law after a decade of debate and rewriting. It went into effect in August 2008. It specifically covered rules to do with mergers and acquisitions of Chinese companies. In addition to general PRC antitrust notifications and reviews that may apply in any significant M&A, under the PRC Anti-Monopoly Law (AML), it is also unlawful for parties to enter into "horizontal" and "vertical" monopoly agreements. Horizontal monopoly agreements include agreements with competitors to fix prices and limit production or sales volumes. Vertical monopoly agreements include agreements between the supplier and its distributors to fix resale prices, or restrict minimum resale prices. When engaging in due diligence of the target, it is important to engage counsel that are experienced in identifying potential violations of such AML provisions.

Regulatory Issues Post-Closing

The restrictions imposed by the China regulatory regime must also be taken into account when considering the post-acquisition structure of the acquired business. In particular:

- Most permits and certifications issued by the SFDA are personal to the entity to which they are granted and therefore cannot be transferred to a different legal entity. Strict eligibility requirements and potentially lengthy application timetables need to be taken

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经常问题

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要收购中国生命科学公司的外国公司对目标公司使用的知识产权开展全面的尽职调查从而评估是否存在未授权使用第三方知识产权的情况是十分重要的。尤其极力建议收购公司对目标公司的关键程序和产品进行自由使用和非侵权分析。

当提到目标公司自有知识产权资产时，知道在中国注册知识产权（例如专利和商标）的执法通常比未注册知识产权（如版权和商业秘密）的执法要容易的多这一点十分重要。鉴于此，对目标公司注册权利的业务组合进行全面审查以评估在保护、纠纷和所有权连续性不完整等方面存在的漏洞是至关重要的。

鉴于相同的原因，与其他司法管辖区相比，在中国对于其核心技术完全或严重依赖商业秘密保护的目标公司很可能面临更大的风险。话虽如此，许多生命科学公司（尤其是生物技术公司和制造企业）将严重依赖业务中包含的技术诀窍是不可避免的。当通过资产转让的方式收购目标公司时，十分重要的一点是约定“技术诀窍”转让的实际安排，而不仅仅是依赖收购协议中泛泛的合法转让。谨慎的收购方可能希望考虑将移交“技术诀窍”作为完成收购的前提条件和/或将其作为购价的一部分。一般而言，协议应规定：

- 移交有关有形文件（包括其建立或校勘，如果现有文档不当）。
- 适当的培训和咨询机制以确保向买方进行彻底的知识转让。
- 保密、披露以及卖方使用限制（这些是十分重要的，与多数其他资产不同，技术诀窍的转让并不是“零和”游戏，因为向收购方进行披露的行为本身并不等于技术诀窍就在卖方的手中消除了）。

合规尽职调查

根据目标公司业务性质不同，针对目标公司营业执照范围和不同产品，在中国开展运营可能需要持有并维持若干个不同的政府批准和许可。买方需开展合规尽职调查以评估目标公司是否遵守不同层次的监管要求，包括：

- **药品进口批准：**在中国分销的所有进口药品须获得国家食品药品监督管理局（药监局）的进口批准。这对医疗设备也同样适用。该等批准按照产品不同予以授予，而且通常将以境外生产商的名义予以授予。
- **药品批准：**在中国分销的所有国产药品需获得药监局的产品批准。该批准同样根据产品不同而授予，但是必须以国内生产商的名义授予（尽管产品可能使用外方许可的或从外方购买的原料药和其他成分）。
- **制药许可：**国内药品生产商必须持有该许可。
- **优良制造标准（GMP）证明：**国内药品生产商必须持有该证明。

反垄断法律问题

经过十年的辩论和重写后，在2007年8月，全国人大常务委员会采纳了国家的首个重大而全面的反垄断法律。该法律于2008年8月生效。其特别涵盖中国公司并购的规则。除可适用于任何重大并购的一般中国反拖拉斯通知及审议外，根据《中华人民共和国反垄断法》（“反垄断法”），有关方订立“横向”和“纵向”垄断协议也是违法的。横向垄断协议包括与竞争对手订立的固定价格及限制生产或销售量的协议。纵向垄断协议包括供应商与其分销商订立以固定重售价格或限制最低重售价格的协议。当对目标公司进行尽职调查时，聘用在认定潜在违反反垄断法的该等规定方面富有经验的法律顾问非常重要。

交割后的监管问题

在考虑被收购业务在收购后的结构时，也必须考虑中国监管机制所加诸的限制。尤其是：

- 药监局出具的大部分许可和证明对获授予的实体均为个人的，因此，不能转让予不同的法律实体。拟采用任何新结构时，也须考虑严格的合资格要求及潜在长时间的申请时间表。
- 如在收购后改变包装，就算收购方仅改变制造商的牌子，将通常

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Frequent Issues

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into account when contemplating any new structure.

- Changes to packaging following an acquisition will usually require further regulatory approval, even if the acquiror merely changes the manufacturer's branding. This must be taken into account when documenting how the product will be migrated to the purchaser. In some cases, a transitional license to use the old branding will be required until the new approval can be obtained.

Consider Effects of a U.S. Acquisition on Sales, Receivables and Bad Debt

Aside from IP and operations, prior to completing an acquisition, it is important to be familiar with the not so obvious issues that might arise, such as:

- **Sales Strategy:** It is common practice for Chinese pharmaceutical companies to outsource sales to third-party distributors that possess specialist knowledge and local, on-the-ground teams. Where a target company has done so, the acquiring company should make sure that the relationship with the third party will remain in place following closing and that the third party will not quickly sell its network of relationships to another company.
- **International Sales Issues:** The U.S. prohibits any U.S. person from involvement in business transactions with certain targeted countries (such as North Korea, Iran, etc.), while PRC companies that are owned and operated domestically do not have the same restrictions. Appropriate due diligence should identify whether the PRC company has business relationships with any persons or entities in such targeted countries, and whether the termination of such relationships would materially affect the company's business.
- **Receivables:** For its domestic sales, consider how much revenue is derived from state-owned entities (like hospitals) vs. non-state-owned entities. While state-owned entities may be unlikely to default on a payment, they may have payment terms as long as six months to a year. On the other hand, privatized or privately owned companies might require more due diligence in terms of ability to pay if payment is not due prior to delivery.

The explosive growth of China's life sciences industry is expected to continue well into the future. However, the drive to close transactions may lead strategic investors to accept risks that are not fully perceived or properly understood at the time of deal execution. In the Chinese M&A market, even the most diligent buyer is rarely afforded the opportunity to conduct a thorough and exhaustive investigation of the target. Notwithstanding such limitations, an awareness of the key issues described above can lead to more constructive negotiations and ultimately a decreased risk of buyer's remorse.

Resources & Further Reading:

- Ministry of Commerce (MOFCOM)
- National Development and Reform Commission (NDRC) of the PRC
- State Food and Drug Administration (SFDA)
- World Intellectual Property Organization
- "China Outlaws Bribery Overseas" by Sherry Yin, Paul McKenzie and Dan Levison, August 8, 2011
- "Protecting Know-How in China: Process Is Simple and Complex" by Andreas Schotter and Mary B. Teagarden, Faculty, Thunderbird School of Global Management, March 15, 2011

Key Regulatory Development

PTO Pilot Program to Speed Patents in China

On November 30, the United States Patent and Trademark Office (USPTO) announced a Paris Route and PCT Patent Prosecution Highway (PPH) pilot program with China's State Intellectual Property Office (SIPO) that became effective on December 1, 2011. The program permits each office to benefit from work previously done by the other, reducing examination workload and allowing applicants to obtain corresponding patents faster and more efficiently. According to SIPO Commissioner Tian Lipu, the program will "promote high-quality patents and expedite processing of patent applications in both offices by avoiding duplicative work and will provide greater costs savings to patent applicants." For further information, see http://www.uspto.gov/news/pr/2011/11-70.jsp.

经常问题

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需要获得进一步的监管批准。在编制产品将如何转移到买方的文件时，必须考虑这点。在某些情况下，将需要使用旧名称的过度许可，直至取得新的批准。

考虑美国收购对销售、应收款及坏帐的影响：

除知识产权及运营外，在完成收购之前，熟识可能引起的不太明显的问题非常重要，例如：

- **销售策略：**中国的医药公司惯常将销售外包予拥有专业知识及本地实战团队的第三方分销商。如果目标公司如此操作的话，进行收购的公司应确保与第三方的关系在交割后仍然存在，而非快速地出售其关系网络予另一公司。
- **国际销售问题：**美国禁止任何美国人与若干目标国家（例如北韩、伊朗等）从事业务交易，但是属于本地拥有及运营的中国公司则没有相同的限制。合适的尽职调查应认定中国公司是否与上述目标国家的任何人或实体有业务关系，以及终止该等关系是否会实质性地影响公司的业务。
- **应收款：**就其本地销售而言，应考虑从国有实体（例如医院）获得的收入相对于从非国有实体获得的收入人别有多少？国有实体较少可能欠款，但付款期限可能长至六个月至一年。另一方面，如果付款在交付前未到期，对私有化或私人拥有的公司可能需要作更多付款能力方面的尽职调查。

中国的生命科学行业的爆炸性增长预期在将来还会有良好的持续势头。不过，由于受完成交易所驱，策略性投资者面临着接受在执行交易时没有完全察觉或适当理解的风险。在中国的并购市场里，就算最勤勉的买方也很少能够有对目标进行全面详尽调查的机会。尽管有上述限制，了解上述主要问题可以使谈判更有建设性，并将最终减少令买方后悔的风险。

资料来源及进一步的阅读材料：

- 商务部（MOFCOM）
- 中华人民共和国国家发展和改革委员会
- 国家食品药物监督管理局（SFDA）
- 世界知识产权组织
- “中国取缔海外贿赂行为”（作者：Sherry Yin, Paul McKenzie和Dan Levison, 2011年8月8日）
- “在中国保护专有技术：过程简单而复杂”（作者：Andreas Schotter 和 Mary B. Teagarden，美国雷鸟管理学院[学系]，2011年3月15日）

主要的监管发展

美国专利及商标局加快中国专利的试点计划

在11月30日，美国专利及商标局（USPTO）公布与中国的国家知识产权局进行的《巴黎路线及专利合作条约专利审批快速通道》（Paris Route and PCT Patent Prosecution Highway）试点计划，该计划于2011年12月1日生效，让每一家办事处从对方已经进行的工作中获益，减少审查工作量并让申请人更快更有效地取得相应的专利。根据国家知识产权局局长田力普所说，该计划将“避免专利申请人的重复工作并节省更多成本以促进高素质的专利及双方办事处的迅速处理专利申请的程序”。如欲获得进一步的信息，见http://www.uspto.gov/news/pr/2011/11-70.jsp。