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安理律师事务所 ANLI PARTNERS 安理向未来

PHARMA FRENZY

A record 271 cross-border licensing deals were signed last year between multinational groups such as Roche, Bayer, AbbVie and Pfizer, and Chinese pharmaceutical companies, according to data from consultancy ChinaBio cited by the Financial Times. The number of deals rose almost 50 percent from 2019 and more than 300 percent since 2015. These collaborations involve clinical development, commercialization and sharing of data of drugs and medical devices.

The rapid growth of China's pharmaceutical market has contributed to the robust cross-border collaborations. "The market is too big and fastgrowing to ignore," says the Financial Times. "Pharmaceutical spending in China totaled \$137 billion in 2018 and will reach \$140 million to \$170 billion by 2023, according to data provider IQVIA."

Lawyers are keenly following this trend. "The life sciences market in China is poised to overtake the largest markets in the world within several years. Some of have predicted that China will become the single largest life sciences market by the end of the decade," says Arthur Mok, regional managing partner of Ropes & Gray's Asia offices.

The Chinese government has also accelerated the opening of the pharmaceutical sector to boost its development through collaboration, as the industry requires very strong capabilities in R&D, financing and commercialization.

In the past few years, the government has been clearing the hurdles for collaborations between Chinese and foreign companies by providing policy incentives, according to Song Wei and Zhang Li, partners at Han Kun Law Offices.

"Since the Foreign Investment Law and its implementation regulations took

China has relaxed restrictions on its healthcare industry, prompting overseas companies to seek access to the world's second-largest drug market. In the past year, a record 271 cross-border licensing deals were inked between Chinese and multinational drugmakers. However, lawyers recommend that potential JV partners should carefully consider certain legal issues before they commit fully.

中国在过去五年中不断开放 医疗健康产业,促使海外药企 来到世界第二大医药市场寻 求合作机会。过去一年,虽然 存在紧张地缘政治关系、知识 产权保护及数据审查矛盾等, 中外药企跨境合作仍然还明 创纪录的271宗。从宏观环境 到细节条款,律师们指出了一 系列合作双方应关注的法律 问题。

BY HU YANGXIAOXIAO 作者: 胡阳潇潇

effect at the beginning of 2020, China has promulgated the Law on Promotion of Basic Medical and Health Care and the Biosecurity Law, and amended the Patent Law. It indicated the opening of the pharmaceutical sector and encouraged foreign investment and pharmaceutical innovation," Song and Zhang tell ALB.

Mo Huan, a partner at Jia Yuan Law Offices, points out separately that the new laws are also helping local drugmakers grow, making them ideal partners for foreign companies.

"In recent years, China has undertaken a series of reforms for the review and approval system of the pharmaceutical industry. It allowed clinical trial approvals by default, implemented the marketing authorization holder system with responsibilities outlined for safety risk during the whole-life cycle of drugs, the two-invoice system, the drug-related associated review and approval system, and the quality consistency evaluation of generic drugs," Mo adds. "In terms of intellectual property, China also introduced a drug patent linkage system and compensation for lost patent terms."

In her eyes, these reforms "support and promote the transformation and upgrading of China's biotech industry." Local drugmakers are encouraged by the new policies to increase investments in innovative drug R&D, while actively looking for new forms of partnerships, such as joining overseas M&As and making licensing deals.

CAPITAL INCENTIVES

There has been an increase in two major types of deals in the past year, the first where Chinese companies will develop and commercialize innovative drug candidates discovered by Western companies, and the second where multinational companies will do the same with cutting-edge Chinese-created pharmaceuticals outside of China, the Financial Times reported.

It cited a number of large deals, including Eli Lilly's partnership with Shanghai Junshi Biosciences to develop a new antibody for COVID-19,

重结其关手

■ 根据英国金融时报援引咨询公 司ChinaBio数据,2020年,罗氏、 拜耳、艾伯维和辉瑞等跨国企业纷 纷与中国制药公司达成合作协议, 总数达271宗,这一数字较2019年 增长近50%,较2015年则增长超 过三倍。合作既涉及临床试验和开 发,也囊括药品器械的商业化及数 据共享。

该领域跨境合作的频繁展开, 得益于中国医药市场的不断发展。 中国市场规模太大、增长太快,不容 忽视。"金融时报指出,"根据数据提 供商IQVIA,2018年中国的医药支 出总额为1370亿美元,2023年最 高将达1700亿美元。

"众多数据及专业人士都预 测,几年内——至少到本世纪20年 代末,中国会成为全球最大的生命 科学市场。"瑞格律师事务所亚洲区 管理合伙人莫雅德律师指出。

与此同时,考虑到医药领域对 于研发、资金、商业化能力等极高的 要求,中国政府也加大了医药板块 的对外开放,希望通过合作方式加 速该领域发展。

在汉坤律师事务所合伙人张漓 律师和宋薇律师看来,过去几年中, 中国政府利用一系列政策法律手 段,不断为中外药企合作铺平道路。

"随着2020年初《外商投资 法》与其《实施条例》生效,中国进 一步施行了《基本医疗卫生与健康 促进法》《生物安全法》,并修改了《 专利法》等,明确扩大医药板块对外 开放,鼓励外商投资和医药创新。" 两位律师告诉ALB。

张律师和宋律师指出,各项细 则颇为振奋人心,例如增加了鼓励 外商投资医药产业的条目、允许境 外企业和科研机构在中国同步开 展新药临床试验,以及在进口化学 新药和生物创新药申请临床和上市 时,取消了应当先在境外所在国获 得上市许可的要求等。





"More common ones include incubation, joint ventures, investments, equity or assets acquisitions, license-in and license-out deals. It's changing from an asset sale to a diversified model that seeks long-term collaboration and distribution of profits."

- Zhang Li & Song Wei, Han Kun Law Offices

"比较常见的合作模式有孵化、 合资开发、投资、股权或资产收购、 授权引进和对外授权等。双方合作 日益从单一买断, 向经济利益长期 合作与分配的多元化模式发展。

- 张漓、宋薇, 汉坤律师事务所

"在此基础上,中国出台的对 境外临床研究数据的接受和进口上 市程序的优化措施,都进一步提高 了外资的投资热情。"两位律师说。

而在硬币的另一边,嘉源律师 事务所合伙人莫环律师指出,各项 政策法规也促进了本土医药企业发 展,使它们成长为外企寻求合作时 恰当的伙伴。

"近年来国内医疗健康行业审 评审批制度进行了一系列改革,包 括临床试验由审批制改为默示许 可、实施上市许可持有人制度和全 生命周期主体责任、两票制、原辅包 与与药品制剂关联审评审批、仿制 药质量与疗效一致性评价等。"莫环 律师列举道,"在知识产权方面,则 增加了药品专利有效期补偿、药品 专利链接制度。"

在她看来,上述改革都"支持并 促使了中国生物医药行业积极转型 升级",一方面,新政促进本土药企 加大对创新药物研发的投入;另一 方面,它们也开始积极寻求商业合 作模式创新,例如参与海外并购、授 权引进等中外合作交易。

资本激活生态

根据金融时报的上述报道,过去一 年中外药企两种"方向"的合作都很 活跃:不但有中国公司积极开发和 商业化西方公司的创新候选药,跨 国公司也在中国以外开发和商业化 中国发明的前沿药物。

报道列举了一系列大手笔交 易:例如美国礼来和上海君实生物 合作开发新冠肺炎抗体疗法;辉瑞 与基石药业合作商业化肿瘤免疫药 物;苏州信达以10亿美元授权礼来 获得肺癌疗法在中国境外的独家权 利;以及天境生物以20亿美元授权 艾伯维获得其实验性抗癌药物。

谈到过去一年自己接触到的中 外药企合作模式,汉坤的张漓律师 和宋薇律师列举道:"比较常见的有 孵化、合资开发、投资、股权或资产 收购、授权引进(license-in)和对 外授权(license-out)等。"而过去 一年的变化在于,"双方合作日益从 单一买断,向经济利益长期合作与 分配的多元化模式发展"。

而在热门领域方面,两位律 师指出,"合作主要集中在创新 药领域,在疫情影响下,新冠疫苗

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and Pfizer's collaboration with CStone Pharmaceuticals to commercialize an immune-oncology drug. Innovent Biologics received \$1 billion from Eli Lilly to license out the exclusive ex-China rights to develop, manufacture and commercialize a lung cancer drug. I-Mab Biopharma also licensed out its cancer drug candidates to AbbVie for \$2 billion.

Speaking of the Chinese-foreign partnership models over the past year, Song and Zhang say: "More common ones include incubation, joint ventures, investments, equity or assets acquisitions, license-in and license-out deals." They add that over the past year, "it is changing from an asset sale to a diversified model that seeks long-term collaboration and distribution of profits."

They point out that partnerships "mainly concentrate in innovative drugs, as well as infectious disease drugs such as mRNA vaccines for COVID-19."

Jia Yuan's Mo sees robust collaboration in oncology and immunology drugs. She says Chinese companies were not very active in overseas M&A in 2020. However, she expects to see more outbound M&A deals by Chinese companies as external factors become less impactful.

In terms of licensing deals, Mo says license-in deals are currently the most common. "We expect to see more license-out deals as Chinese companies enhance their R&D capabilities and foreign players pay more attention to R&D in China," she adds.

Ropes & Gray's Mok points out an interesting trend that joint venture structures are becoming popular again.

"Joint venture structures were common in the past due to limitations on foreign investment. With the relaxation of such limitations within the last decade, joint ventures fell out of favor. Recently, however, there has been a resurgence of joint venture structures and in fact are often considered the favored structure for both Chinese and foreign firms pursuing innovative approaches to accessing or expanding the market for new or innovative drugs or therapeutic products," Mok says.

Ropes & Gray began revisiting joint

venture structures back in 2012 and 2013 for localized development of innovative drug products, Mok tells ALB. "But those initiatives were early for their time as the eco-system of accessible assets, experienced entrepreneurs, sector focused investors, and highly active regional capital markets was still in the process of ripening."

Mok says the ecosystem is now ripe. "Multinational companies can build brand new companies using pharmaceutical assets outside of China to become the core of these new companies and then hire local or regional talent to run the businesses. Investors involved in private equity, growth equity and venture capital who specialize in life sciences investments are willing to support the industry. New companies can attract third-party capital to finance the business and ultimately take the business public, either in mainland China or Hong Kong. "It gives these equity platforms a significant advantage," he adds.

Song and Zhang share Mok's view. They note that more capital not only prompts a booming pharmaceutical market but also "drives the growth and upgrading of the upstream and downstream industries, including the active pharmaceutical ingredient sector, contract research organizations, contract development and manufacturing organizations (CDMO), AI-assisted drug development and 3D printing. All these business ecosystems are seeing new opportunities."

WIN-WIN

Mok notes that logistical and other barriers created by the COVID-19 pandemic have forced pharmaceutical firms worldwide to rethink their operations, ranging from global R&D strategy to supply-chain management. Chinese firms have demonstrated their value during this period and have become increasingly more important partners for foreign firms.

As an example, Mok notes that prior to the onset of the pandemic, numerous China-based pharmaceutical companies embarked on an aggressive campaign to expand their biologics development

and manufacturing capabilities. "With the pandemic, the world was hunting for capacity to manufacture biological products as there wasn't sufficient near-term manufacturing capacity for novel vaccine products," he adds. "The pre-pandemic biologic production capacity expansion in China attracted a lot of interest from multinationals."

Additionally, "China was well known for having reliable contract manufacturing organizations [CMOs]. With the advent of CDMOs in China, local partners in the market are positioned to assist global, regional and even Chinese companies in the small molecule and biologic development process, in addition to manufacturing products," says Mok. "China is very well positioned to become a leader in the CDMO space."

Apart from making use of the production and R&D capabilities of Chinese firms, the joint venture structure also benefits multinationals in other ways. The structure helps multinationals navigate the regulatory pathways in China, potentially access expedited review for regulatory approvals, and facilitate a broader range of capital partners to finance operations, he adds.

Mok also notes that multinational drugmakers have grown increasingly interested in Chinese biotech startups in recent years. "I think they're looking at Chinese biotech startups as its hard to ignore the fact that innovation is happening here," he says. "In China for China" has become more than just a marketing mantra, it's become a reality. By partnering with startups, multinational drugmakers "get opportunities, not only to access innovative potential local products, but also to potentially partner with businesses that could in the future become acquisition targets or become important commercial partners for the market."

KEY LEGAL ISSUES

Collaborations between multinational and Chinese pharmaceutical companies also require support from lawyers. Lawyers share what legal issues they pay attention to.

Song and Zhang first point out the importance of intellectual property.

(mRNA技术)等感染领域的药物 研发也成为重点"。

嘉源的莫环律师则观察到了 肿瘤和免疫领域药品项目的活跃 合作,而谈到过去一年偏好交易模 式的变化,她指出,2020年中企海 外并购不算活跃,但伴随外部因素 影响减弱,中国医药行业海外并购 数量预期将增长。

在许可交易方面,莫环律师 指出,目前中国引进国外技术的 license-in模式仍占绝对优势,"但 随着中国企业药物研发实力增强, 以及海外企业对中国药物研发的关 注,预计中国企业日后license-out 的交易会逐渐增多"。

瑞格的莫雅德律师则观察到了 另一个十分有趣的趋势,即合资公 司重新受到青睐。"由于外商投资 受限,合资结构曾经很普遍,随着过 去十年中对外商投资限制的不断放 松,合资模式也不再受到欢迎。然而 最近几年,中外企业在寻求创新模 式,以打开或扩展新药、创新药、治 疗产品的市场时,我们发现合资结 构实际上重新成为了大家最偏好的 交易结构之一。"莫律师指出。

莫律师告诉ALB,瑞格团队在 2012年前后在本地化创新药产品 项目中"重新启用"了合资模式," 但对这种模式来说还为时过早,因 为由医药资产、有经验的企业家、专 注领域的投资者,以及极富活跃度 的地方资本市场所组成的牛态圈还 尚未成熟"。

他指出,生态圈的成熟首先体 现在前端:跨国公司可以将医药资 产注入新公司,同时在中国寻找到 优秀的本土管理和科研人才支持合 资公司后续运营;而在后端,由于私 募基金、成长型基金、风险投资和资 本市场都对生命科学表现出极强的 支持意愿,新公司可以不断吸引到 第三方投资,最终在上海科创板或 香港实现上市,"这使得资本平台极 具优势",莫律师说。

张漓律师和宋薇律师同样认可 莫律师的观察,她们指出,资本的活 跃不但引发了医药领域的蓬勃发 展,甚至"进一步带动相关上下游 产业的飞速发展和升级,包括原料 药、CRO、CDMO、药物AI研发、3D 打印等,这些大小业务生态圈都迎 来了新的发展机遇"。

此外,"国内医院医疗机构和大 学科研机构也更积极地成为生态圈 参与方,许多早期医药技术成果甚 至都开始成为商业合作转化的资产 目标",两位律师说道。

嘉源对于资本激活医药产业生 态也有着第一手观察。嘉源高级合 伙人王元律师告诉ALB,"虽然国 内初创型生物医药企业盈利能力 不高,但投资者普遍看好其未来成 长性"。因此,在一级市场,生物医药 行业一直是PE/VC近年投资的热门



"Chinese companies were not very active in overseas **M&A in 2020... We expect** to see more license-out deals as Chinese companies enhance their R&D capabilities and foreign players pay more attention to R&D in China."

- Mo Huan, Jia Yuan Law Offices

"2020年中企海外并购不算活 跃……随着中国企业药物研发 实力增强,以及海外企业对中国 药物研发的关注,预计中国企业 日后license-out的交易会逐渐 增多。"

- 莫环, 嘉源律师事务所

赛道,"尤其是pre-IPO或交叉轮融 资,更是投资人的热点"。

而在二级市场,"随着港股 18A、科创板第五套标准的实施,近 三年国内创新型医药企业迎来了一 波上市热潮",王律师说,嘉源先后 参与了君实生物H股和科创板上市、 复星医药分拆复宏汉霖H股上市、泰 格医药H股上市等项目,"预计未来 会有越来越多A股医药企业随着国 际化发展,实现多地上市"。

互相成就

莫雅德律师指出,疫情引发的物流 及其他问题迫使全球医药企业重新 思考扩大运营范围——其中既包括 采取全球研发策略,也包括扩大产 业链管理范围。在此过程中,中国 企业展现出了更高价值,表明自身 已成为外国医药企业不可忽视的合 作伙伴。

举例来说,莫律师注意到,疫情 初期,大量中国医药企业开始加速 扩张生物制剂研发及生产能力。"疫 情下,全球医药企业都意识到了全 新疫苗产品的近期生产能力不足。' 莫律师说,"而中国在前疫情时期扩 展的生物制造能力引发了跨国企业 的极大兴趣。"

此外,"过去中国最出名的是可 靠的CMO,即合同加工外包模式。而 伴随CDMO,即合同研发生产模式 的发展,本土企业现在能够在小分 子和生物制剂研发过程中助全球、 区域、甚至中国药企一臂之力,而不 仅仅是从事生产而已。"莫律师说, 中国已做好充分准备,成为CDMO 领域的领头人。"

除了运用中国企业的生产和研 发能力,以合资结构寻找中国合作 伙伴还能为跨国药企带来其他切实 好处,例如更为有效地建立合规体 系、潜在获得更快速监管许可的可 能性,以及吸引更为广泛的投资伙 伴,莫律师指出。

他还观察到,近年来跨国药企 开始对中国初创药企产生越来越浓 厚的兴趣。谈及背后原因,莫律师指 出:"他们无法忽视:真正的创新正 在中国上演。""立中国,利中国"不 再只是句商业口号,而成为了现实。 通过和初创药企合作,跨国药企"不 仅能够就创新产品展开合作,还能 和相关企业结成伙伴,而这些企业 未来可能成为潜在收购对象"。

核心法律问题

医药领域中外合作如火如荼展开, 离不开法律专业人士的保驾护航。 在律师看来,合作双方近期重点关 注的法律问题又有哪些?

张漓律师和宋薇律师首先提到 了知识产权问题。"在医药行业的许 可合作中,知识产权往往是双方合 作的核心。"两位律师说,"首先是知

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"Intellectual property tends to be the core of licensing deals in the pharmaceutical industry," they say. "First is the ownership of intellectual property. Due to the dynamic nature of pharmaceutical partnering, are licensees allowed to improve and further develop the patented technology? Issues including how to allocate ownership and benefits of intellectual property of the improved technology and how to stipulate the granting of rights clauses and service inventions need to be clarified in licensing agreement to avoid any disputes."

At the same time, intellectual property protection needs attention. "In past experience, there were cases where no one defended their rights against infringement of third parties," they point out. However, as China has formally established a drug patent linkage system, marketing approval applicants and patent rights holders or stakeholders can solve patent ownership disputes through judicial or administrative channels.

Another key legal issue is related to data compliance.

"When talking about drug development, it often involves global registration studies as well as clinical studies within China. The process relies upon collaboration and sharing of data across borders," says Mok. "But it's becoming more complicated these days in navigating the regulatory terrain for multiregional trials."

"China has strengthened its legislation and law enforcement of healthcare data collection and storage in recent years, especially for cross-border data transmission," Song and Zhang explain. "Healthcare data should only be stored within domestic servers by principle. Security assessments and reviews are needed when data needs to be transferred overseas due to business requirements. It will be prohibited once the data shows population health information."

Things get more complicated when biological specimens or genetic data are involved. "Both the Biosecurity Law and the draft Personal Information Protection Law released in 2021 regulate the protection and rational use of human

genetic resources and personal information," they say. "It somehow blocks the accelerating collaboration between Chinese and foreign firms."

Therefore, they suggest that both parties should be careful about the forms of participation if human genetic resources are involved. If not, "it just needs to be put on record instead of an approval by the authorities." They also say companies "should keep an eye on special provisions related to human genetic resources, such as the opening of data during the research process, patent ownership, major alterations, among others."

The third legal issue relates to export control regulations and antitrust practices. According to Mok, certain therapeutic assets and technologies could be considered as "sensitive" technologies by governmental authorities. As such, "it's important to carefully consider whether assets that are contemplated to be contributed or licensed into the joint venture will require an export license or some other form of government approval." Both the PRC and US governments have been more assertive in evaluating national security considerations in respect of these cross-border partnerships, particularly where breakthrough or innovative technologies are involved. Beyond such geopolitical consideration, Mok also notes that there are customary tax as well as antitrust considerations to consider if the transaction involves equity and/or cash investments.

EXPANDING ROLES

Law firms are will likely get more opportunities as collaboration between foreign and Chinese companies continues to stay robust. There are multiple opportunities for lawyers to provide quality services.

Song and Zhang point out the uniqueness of legal risk points. "Investments, as well as M&As in pharmaceutical firms, tend to be more complicated, where risk points are difficult to perceive," they say. "We pay special attention to and assist customers in analyzing and solving typical and atypical legal risk points, such as business compliance, intellectual property, key

technical personnel, scientific research projects and subsidies and product requirements for corporate listings. We will provide customized legal services during different phases from being incubated to getting listed by resolving transaction structures and lowering risks."

Jia Yuan Law Offices also provides "one-stop services" for startups as well as listed companies. Yang Yuan, senior partner at Jia Yuan Law Offices, tells ALB that the firm has expanded its business to provide comprehensive services for pharmaceutical firms. For example, "we noticed the importance of intellectual property-related issues after talking to our clients. Thus, we brought in an intellectual property partner with extensive experience in the healthcare sector to help our clients deal with intellectual property issues, to identify intellectual property risks and provide solutions."

Lawyers should help clients control big-picture risks, especially considering the current geopolitical and economic landscape, says Mok.

"We have seen more inquiries from clients with a higher level of need to understand what the risks are for them to do transactions or conduct business in China," he says. "There are a lot of concerns about what Chinese companies can do within the U.S. There are also equal concerns now about what US companies can do with respect to licensing their technologies for development within China. Thus, we spent a lot of time looking at national security issues."

However, Mok notes that multinational companies continue to take the long-view with respect to China.

"The experienced participants in the market are willing to consider a broader range of options to ensure their long-term presence and success in China, even if there is increased geo-political tension. It's a bit of going back to the future from the past with joint venture structures. Multinationals are able to localize their business interests while maintaining visibility on operations and some level of control. These structures address the world we live in, which is moving in a direction that requires flexibility on approach," he adds.

识产权归属问题,医药合作是个动 态过程,被许可方是否有权改进和 进一步研发专利技术?改进后的知 识产权权属和收益如何分配、权利 回授条款如何设置、职务发明等问 题都需要在许可协议中明确,否则 极易产生争议。"

此外还有知识产权保护问题。 两位律师指出:"在以往合作中,存 在第三方侵权而无人维权的尴尬情 景。"而随着国内正式推行药品专利 链接制度,药品上市审批过程中,上 市许可申请人与专利权或利害关系 人就可以通过司法或行政途径解决 相关专利权纠纷。

另一个核心法律问题则存在于 数据合规领域。

"谈到新药开发,通常涉及中 国境内的登记研究和临床研究,过 程中通常要涉及合作及跨境数据分 享。"莫雅德律师说,"现如今,探索 这一领域的合规问题对于跨区域临 床试验项目来说正变得愈发复杂。'

"中国近年来加强了医疗数 据收集和储存方面的立法和执法 力度,对于数据跨境传输尤其持谨 慎态度。"张漓律师和宋薇律师解释 说,"健康医疗大数据原则上应当存 储于境内服务器,因业务需要确需 向境外提供的,应依法进行安全评 估审核,一旦医疗数据属性上构成 人口健康信息,其跨境传输活动将 被严格禁止。"

如果涉及到牛物样本或基因信 息,情况更复杂。"《生物安全法》以 及2021年出台的《个人信息保护 法》审议稿,都对人类遗传资源和个 人信息的保护和合理利用进行了规 制。"两位律师介绍道,"这对中外企 业的加速合作构成一定障碍。"

她们因而提醒,如果合作涉及 人类遗传资源,中外双方需要注意 参与形式。她们还建议"关注与人类 遗传资源相关的特殊条款,例如研 究过程中产生的数据信息的开放以 及专利权归属、重大事项变更等"。

第三类法律问题则集中于出口 管制和反垄断领域。莫雅德律师指 出,由于部分医药资产和技术可能 被政府视为"敏感"技术,"在考虑将 某些医药资产授权给合资企业时, 尤其要注意是否需要出口许可或其 他形式的政府许可"。特别是涉及突 破性或创新性技术时,现在中美政 府在审批此类跨境合作时,都尤为 强调国家安全因素。

此外,莫律师还强调,当有股权 或现金投资介入时,"还需要考虑关 税和反垄断问题"。

大块的法律问题之外,律师们 发现合作双方在交易文件细节上也 有更多考量。张漓律师和宋薇律师 指出,例如在授权引进合作中,"双 方成本核算和利润分配往往会采取 更为复杂的计算和支付机制,包括 首付款、研发里程碑款、商业程碑



"There has been a resurgence of joint venture structures and in fact are often considered the favored structure for both Chinese and foreign firms pursuing innovative approaches to accessing or expanding the market for new or innovative drugs or therapeutic products."

- Arthur Mok, Ropes & Gray

"中外企业在寻求创新模式,以打 开或扩展新药、创新药、治疗产品 的市场时,我们发现合资结构实际 上重新成为了大家最偏好的交易 结构之一。"

- 莫雅德, 瑞格律师事务所

款、许可使用费、分许可费等,需要 对合作协议中的相关条款做出更清 晰的规定,并设置合理的争议解决 方式。"两位说,"协议是否能约定充 分、司法实践是否能给予保护,是合 作方普遍关心的问题。'

莫雅德律师对此表示认同,"大 家开始把这类合作当作真正的商业 机构去运营",这意味着合资企业的 股东们要规划好企业治理、合规、劳 动用工、运营、知识产权策略,以及 股权激励等各类问题,"作为资产平 台的合资企业是个真正的生意,而 不只是个虚拟的平台"。

律所服务

中外医药企业合作预期继续活跃,律 所也面临更多业务机会。对于持续提 供优质服务,律师们又有哪些思考?

张漓律师和宋薇律师首先指出 法律风险点的独特性问题。"对医药 企业的投资、并购往往更为复杂,有 的风险点不容易被觉察。"她们说," 我们会特别关注并协助客户分析解 决典型和非典型法律风险关注点, 如业务合规、知识产权、核心技术人 员、科研项目与补贴及企业上市对产 品的要求等,并通过交易架构化解、 降低风险,在客户的孵化直至上市 的不同阶段提供定制化法律服务。"

从初创到上市,为企业不同阶 段提供"一站式"服务也是嘉源的 策略。嘉源高级合伙人傅扬远律师 告诉ALB,为此,嘉源拓展了服务领 域,争取为医药企业提供"全领域" 服务,例如"在和客户交流中,我们 发现知识产权相关事项对该行业客 户的重要性,因此引进了在医疗大 健康领域有丰富经验的知识产权合 伙人,以协助客户处理知识产权问 题、识别知识产权风险并提供解决 方案"。

莫雅德律师则指出:尤其考虑 到当下的国际政经背景,相关领域 律师应帮助客户从更宏观的角度把 控风险。

"许多跨境合作都存在于中美 药企之间,客户开始越来越多询问 到和在中国做生意相关的一些高层 次问题。"莫律师坦言,"美国客户很 关心自己是否能将特定技术授权到 中国,中国客户也想知道他们在美 国做生意究竟会受到怎样的限制。 我们花了很多时间来解答这类国家 安全性问题。

不过,莫律师认为跨国药企仍 会从长期视角看待中国。"即使地缘 政治加速紧张化,有经验的市场参 与者仍希望寻求更多选择,保障他 们在中国市场的长期驻扎与成功。 借助合资模式,跨国药企可以在保 留运营能力和部分控制权的同时将 业务本地化。这种模式恰好反映了 我们所生存其中的世界:保持灵活 方为长久之策",他说。