Acquisitions of Technology Companies

ACC Association of Corporate Counsel NORTHEAST

ROPES & GRAY

AGENDA

- **Welcome Remarks**
- **Full Group Session – Overview of Technology M&A Trends and Hot Topics**
  - Technology M&A Trends
  - Biotech M&A Trends
  - Hot topics affecting tech/biotech acquisitions
  - Antitrust clearance process/regulatory issues
  - CFIUS
  - Data Privacy & Cybersecurity
  - COVID Considerations
- **Breakout Sessions**
  - Technology, Media & Telecommunications-Specific Considerations
  - Life Sciences-Specific Considerations

Office location slide

2021 Technology Practice Group of the Year

Ranked across technology-focused fields including “Privacy & Data Security,” “Intellectual Property: International Firms” and “Corporate M&A”

Information Technology Law

Named to 2017 *Pro Bono* Hot List

Named one of most innovative firms in North America and Asia

One of eight firms with best associates

“Deal of the Year 2020” Qorvo Acquisition of Decawave Limited

2020 Pan European TMT League Tables by value Ranked #1

Ranked in 32 practice areas

Ropes & Gray M&A By the Numbers

Ropes & Gray's award-winning M&A practice is regularly ranked among the world's leading practices by *Chambers*, *The Legal 500* and *U.S. News*, among others. With over 250 M&A attorneys located in the United States, Europe and Asia, our practice offers global scope and on-the-ground service where and when needed.

In 2020–2021, Ropes & Gray navigated more than 550 M&A transactions with an aggregate deal value of $500+ billion, winning *The American Lawyer*'s "Dealmakers of the Year."

Depth of Experience:

- **550+** Announced transactions in 2020–2021
- **$500b+** in total transaction deal value in 2020–2021
- **80+** Industries and sectors

A Market Leader:

2021 Deal of the Year
(Dunkin' Brands' $11.3b sale to Inspire Brands)
Franchise Times

Dealmakers of the Year 2021
The American Lawyer

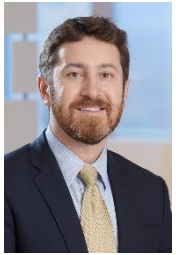
2020 Deal of the Year
(Qorvo's acquisition of Decawave)
The Irish Times

Our Commitment:

350+	250+	150+	12
Specialty-support lawyers	M&A lawyers	Years of practice history	Offices to support deals

Ropes & Gray Team

Chris Comeau
Boston
Partner, M&A



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Partner, VC/EC

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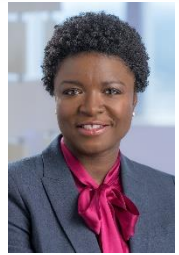

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Technology M&A Trends

- Tech deal activity in 2021 increased 27.3% from 2020 (total deal value of approximately $293.2B), with deal volume up 22.6% (1,763 deals) at an average deal size of $157.9M.

Technology M&A Trends

- **Strategic tech acquirors**
  - Microsoft proposed acquisition of Activision
  - Okta acquisition of Auth0
  - Salesforce acquisition of Slack
- **Financial Sponsors/PE/nontech acquirors**:
  - Cloudera acquisition by Clayton/KKR
  - Talend acquisition by Thoma Bravo
  - McAfee acquisition by Advent/Permira
- **SPAC deals** – lots of tech companies going public via de-SPAC transactions

Technology M&A Trends

- **Tech disruption**: AI, IOT and cloud-based computing have disrupted traditional industries like healthcare, advertising, automotive, banking, leading to “hybrid-tech” consolidations
- **Hot industries:**
  - Cryptocurrency
  - Healthtech
  - Energy storage
  - Metaverse
  - Software security

Biotech M&A Trends

- **Drivers** (no material change from recent past)
  - Large pharma filling development pipelines and in some instances branching
  - Development timelines and cost force constant finance, partner or sell considerations
  - Range from early stage (Lilly acquisition of Prevail) to commercial/late stage (Merck acquisition of Acceleron)
- **SPACs** (some, but fewer than tech)

Hot Topics Affecting Tech/Biotech Acquisitions

Representation and Warranty Insurance vs. Indemnity:

- General
  - Market trend towards RWI in private transactions.
  - Traditional Seller Indemnity
    - A promise to indemnify the buyer in respect of specified losses, should they arise
  - Rep & Warranty Insurance
    - An insurance policy purchased in connection with an M&A transaction, which pays the buyer for losses in the event that a breach of a representation or warranty contained in the purchase agreement is discovered post-closing
    - Used to either ***replace*** (typically) or ***supplement*** a seller indemnity

Hot Topics Affecting Tech/Biotech Acquisitions

- Pros/Cons of RWI
  - Pros
    - Sellers benefit from limited post-closing exposure and smaller escrow or holdback of a portion of the purchase price (if any at all)
    - Broader representations/easier transaction process
    - Longer coverage periods
    - Buyers can offer the above benefits to sellers, enhancing Buyer's position as a transaction partner
  - Cons
    - Policy exclusions, including in particular for known issues discovered in due diligence
    - Risk of no coverage for known items
    - No coverage for interim covenant breaches or items discovered prior to binding the policy
    - Limitations imposed by the due diligence process
      - Required to share buyer due diligence with insurer
      - No clear attorney-client privilege/common interest between buyer and insurer

Hot Topics Affecting Tech/Biotech Acquisitions

- Key Terms
  - Coverage
    - Approximately 10-20% of purchase price / enterprise value of the target
    - Higher percentages, up to 100%, sometimes available depending on the deal and subject to aggregate coverage limits
    - Lower percentages common on larger (>$750M) deals

Hot Topics Affecting Tech/Biotech Acquisitions

- Pricing
  - Typical premiums range from 4.75% to 5.75% of the policy coverage limits
    - All in costs (including taxes and fees) typically 5% to 6%
    - Deals involving smaller targets (purchasing less than $5M of coverage) and targets in highly regulated industries (e.g. healthcare, fintech) tending to price at the higher end of the range and even above
    - Premium rates higher for deals with EV over $500M but tend to trend downward with increased purchase of policy limits

Hot Topics Affecting Tech/Biotech Acquisitions

- Pricing (cont.)
  - Typically no up-front fee for broker to get initial indications from insurers
  - Other Costs:
    - $40,000-50,000 non-refundable diligence fee generally required to get insurer engaged; Non-refundable and not credited towards premiums
    - 10% of premium payable to lock-in coverage at signing; Holds coverage between sign and close; Generally non-refundable, but credited towards remaining amount of premium payable at closing
  - Retention/Deductible
    - Typically ~1% of purchase price but varies based on specific terms of coverage and results of due diligence
    - Often can get deductible to be reduced after 12-18 months to 0.5%

Antirust Clearance Process/ Regulatory Issues

- Increased regulator scrutiny leads to more uncertainty, longer timelines to closing; strong skepticism at the agencies toward big tech and big pharma
- Reverse termination fees
- HSR
  - If size of person/transaction tests are met filing is required
  - 30 day waiting period for mergers (15 for cash tender offers); frequently doubled through “pull and refile” procedure. No early termination.
- FTC skeptical about agreed remedies; imposing prior approval requirements in consent decrees

Antirust Clearance Process/ Regulatory Issues

- Litigation is always an option; can be important to have the threat of litigation in negotiation with agencies
- Divestiture to solve competitive overlap only works if there's an acceptable divestiture buyer out there.
- Export compliance/approvals
- Ex-US agencies also ramping up enforcement

CFIUS

Committee on Foreign Investment in the United States

- Reviews certain foreign investments that implicate U.S. national security concerns.
- Failure to notify CFIUS of a transaction can result in significant risk where meaningful national security issues are involved.
  - If CFIUS finds a credible threat to national security, it may recommend that the President suspend or prohibit the transaction, or impose mitigation measures.
  - No SOL if you fail to notify CFIUS and they later decide the transaction implicates national security.

CFIUS

- CFIUS Jurisdiction
  - Historically, CFIUS's jurisdiction was limited to transactions that could result in a **foreign person** exercising control over a **U.S. business.**
  - 2018 legislation significantly expanded CFIUS's jurisdiction to include non-controlling, non-passive investments by a foreign person in TID U.S. businesses (i.e., U.S. critical technology, critical infrastructure, or sensitive personal data business) that provide the foreign person:
    - Access to any material non-public technical information;
    - Membership or observer rights on the board of directors or an equivalent governing body of the business or the right to nominate an individual to a position on that body; or
    - Any involvement, other than through voting of shares, in substantive decision-making.

Cybersecurity

- Three big threats to watch
  - Ransomware
  - Supply chain
  - Insider threats

Data Privacy & Cybersecurity: EU, U.S. & China

EU

Human Rights

- Data Privacy and Cybersecurity in the EU are currently governed by two main laws:
  - **The General Data Protection Regulation ("GDPR")**
    - Applies to the processing of personal data
    - Maximum penalty = **EUR 20 million** or **4%** of worldwide annual turnover (whichever is higher)
  - **The Network and Information Systems Directive ("NISD")**
    - Applies to the processing of personal and non-personal data
    - Maximum penalty = **GBP 17 million**
- The **EU Cybersecurity Act** came into force in June 2019. The Act:
  - Introduces an EU-wide cybersecurity certification framework for services and devices

USA

Consumer Protection

- **Federal Trade Commission Act and Sectoral Patchwork**
- **California Consumer Privacy Act** to come into force on 1 January 2020:
  - Governs the processing of consumers personal data
  - Maximum penalty per violation (i.e. **not** per event) = USD 7,500

China

Data Sovereignty

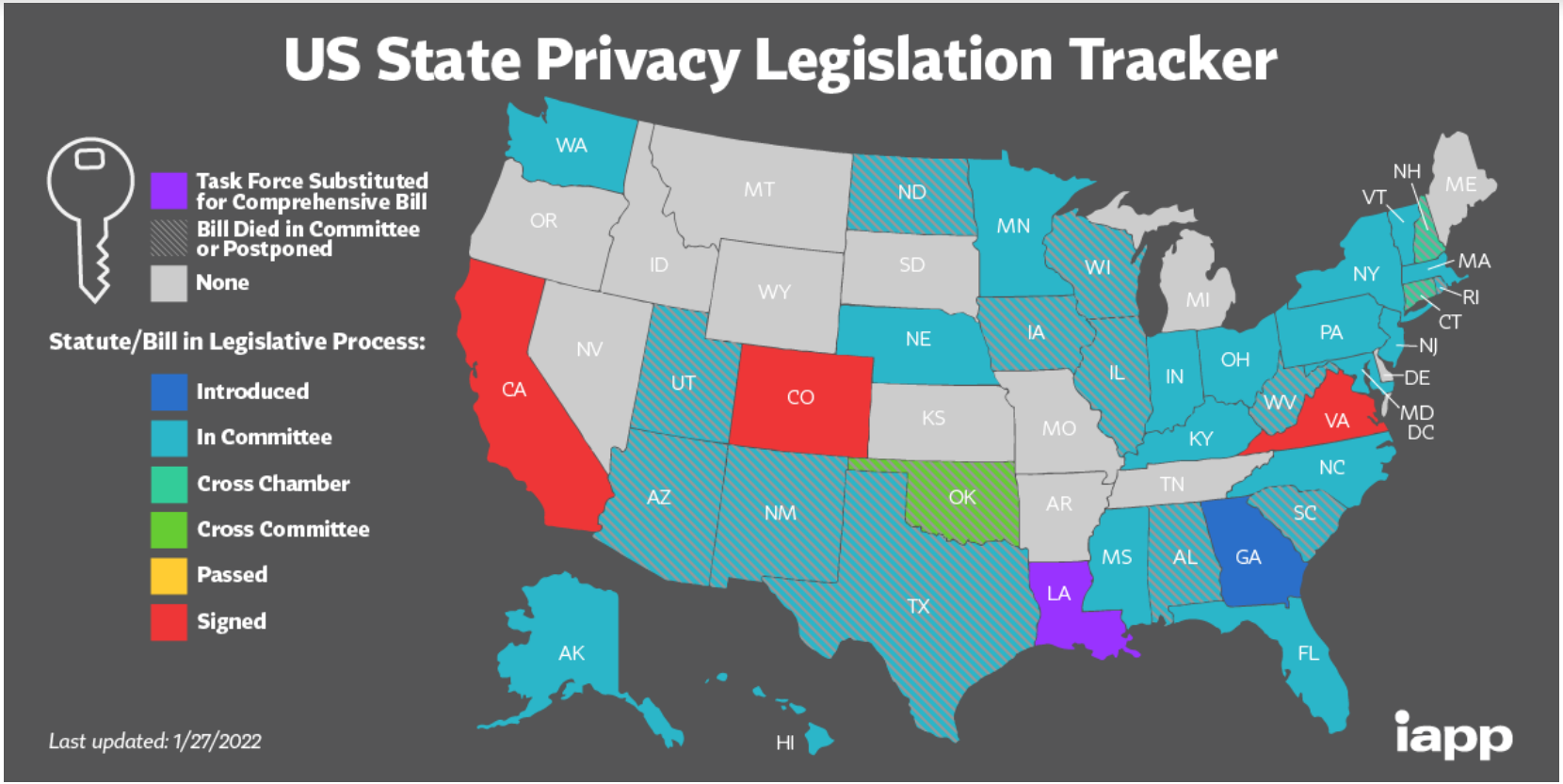
- **Personal Information Protection Law ("PIPL")** came into force in 2021:
  - Applies to the processing of personal data, excluding anonymized data
  - Maximum penalty = **RMB 50 million** (-GBP 5,804,600 or USD 7,851,400) or **5%** of annual turnover
- **Cybersecurity Law** came into force in 2017:
  - Governs the processing of personal data and cybersecurity of network operators
  - Maximum penalty = **RMB 1 million** (-GBP 116,092 or USD 157,028)
- **Data Security Law** came into force in 2021:
  - Governs the processing of personal and non-personal data
  - Maximum penalty = **RMB 10 million** (-GBP 1,160,920 or USD 1,570,280)

AdTech Continues to Move Faster than the Law

- Advertisers are moving past cookies
  - Google launched topics, to replace cohorts, to replace cookies
  - Belgian DPA rejects IAB; Google Analytics under attack
- FTC FLO and Mass General cookies
- Range of alternative methods of performing tracking online include:
  - device fingerprinting
  - browser fingerprinting

  Expansion of tracking is likely to continue as more devices connect to the internet (IoT, vehicles, etc.). New IoT and online tracking capabilities pose much greater risks in terms of systematic monitoring and tracking of individuals, including online behavioral advertising.
- Assess advertising and data acquisition partners

Other State Developments



COVID Considerations

- Carving out the effects of Covid-19/pandemics from the definition of Material Adverse Effect
- Conduct of the business between signing and closing (AB Stable VIIII v. MAPS Hotels)
- Disclosure regarding effects of Covid-19
- Repayment of PPP loans

Other Considerations in Tech M&A

- **Banker engagement letters**
  - Considerations regarding structured transactions
- **Shareholder considerations**
  - Managing communications
  - Challenges with deferred consideration deals vs. more upfront when interests are mis-aligned
- **Management equity incentive considerations**
  - To vest or not to vest, that is the question
  - Where management performed, but equity doesn't provide deserved payout, boards will create "carve out" plans
  - Where plan doesn't provide for automatic vesting on a change in control, boards have a decision to make; might not be all or nothing.

BREAKOUT SESSIONS

Technology, Media & Telecommunications-Specific Considerations

Privacy and Data Security Diligence

- Cybersecurity – Major threats from ransomware, supply chain, insider threats
- SEC focus on data governance at public companies
- New data privacy regime in China reflects aim to assert control over foreign and domestic tech companies and their data
- Ad tech revolution – Europe (Austria, Netherlands, Belgium) have begun to challenge Google Analytics, IAB media terms as non-compliant with EU data privacy schemes/GDPR

Privacy and Data Security Diligence

- Maintaining interoperability in data collection, use and storage; compliance with privacy and data security laws in various jurisdictions (GDPR, CCPA, etc.);
- Machine learning, artificial intelligence and purpose limitations
- Data protection and the blockchain
- Use of data trusts as data fiduciary –Placing data in a trust structure provides greater flexibility for data use, collection, analysis
- Rise of Ethical Privacy

Data Partnerships and Trusts

- Covid has accelerated and matured data partnerships
- Intermediating data collection through special purposes non-profits may diminish privacy concerns associated with government data sharing
  - e.g. National Center for Missing and Exploited Children (“NCMEC”)
- Data Trusts: independent, non-governmental third party that manages data in accordance with defined principles
  - Exempt from CCPA
  - Sharing data for app/tech development or other purposes subject to trust’s approval
  - Ensure data is destroyed and not repurposed
  - Consistent with next-level ethics focus

A third wave of privacy

- Baseline rules on the horizon
  - Independent of notice and choice
  - Focused on specific data abuses
  - Regulation of collectors of information
  - Regulation of data brokers
- Data fiduciaries

Getting ahead of the wave

- Data governance can be a differentiating factor in gaining consumer, patient and healthcare provider trust
- Focus on ethically-based use of data
  - Avoids areas deemed to be abuses
  - Delivery of relevant information without profiling
  - Data protection impact assessments
- Ensure Robust data mapping
- Limit dependence on personal data sale ecosystem
- Move toward robust consumer controls

IP Issues – Technology Companies

- Chain of title issues (including IP assignments, prior inventions, conflicting obligations of consultants)
- Protection of Confidential Information/Trade Secrets
- Open Source issues
- Remediation of potential licensing irregularities (e.g., non-compliant sublicenses, exclusivity, joint ownership and development)
- Consents from third-parties
- Freedom to operate (FTO) considerations

Life Sciences-Specific Considerations

Process: Project Trojan Horse

- Not uncommon for targets to initiate a collaboration agreement process and find M&A at the end of that rainbow; might be a strategy
- Actual, engaged competition in M&A processes is relatively rare

Information Sharing / NDAs

- Clean team considerations, sharing competitive/sensitive information
- Staging and building the data room
- Protection of Company data subject to GDPR (employee files)
- Common interest privilege / sharing FTO opinions and similarly sensitive IP information
- Non-solicits
- Standstill provisions

MAE exceptions / closing certainty

- Buyer doesn’t have to close if there has been a “material adverse effect” on the target
- Each deal involves some negotiated exceptions to that; recent trend in public deals has been toward some form of super-broad carve-out, shifting substantial risk to buyers

Special antitrust considerations: potentially long deal timeframes

- Antitrust environment creates potentially long deal timelines.
- Targets need to be financed through the process and through a successful post-deal-break pivot
- Buyers frequently providing financing as a trade to get targets to accept long timelines
- Holding a company together for 18 months to see if a deal closes is not fun, particularly if it doesn't.

280G gross-ups in public target transactions

- Management teams moderately successful in getting buyers to agree to accept gross up of management team members with parachute payment tax penalties
- Negotiating dynamics are challenging; need to negotiate management terms after agreeing on price with buyer

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IP Issues

- Scope and strength of patent protection, including estimated loss of exclusivity (LOE) dates
- Chain of title issues (including patent assignments and conflicting obligations of consultants)
- Freedom to operate (FTO) considerations
- Diligence of and the potential need for amendments to material upstream licenses
- Remediation of potential licensing irregularities (e.g., non-compliant sublicenses, missed diligence milestones)
- Consents from third-parties

QUESTIONS

THANK YOU

ROPES & GRAY

PERSPECTIVES

PRIVATE EQUITY INDUSTRY INSIGHTS

SPRING 2021

WELCOME TO THE SPRING 2021 ISSUE OF *PERSPECTIVES.*

The past year has been a roller-coaster ride for private equity, as the industry navigated the ups and downs of the global pandemic and adjusted to major political changes across the globe, including a new administration in the U.S. and the withdrawal of the UK from the EU. As COVID-19 (hopefully) nears its end, and as the political climate settles, private equity investors and their portfolio companies are gearing up for the many opportunities and challenges ahead.

In this issue of *PErspectives*, we offer our clients a glimpse into the future. We open with a detailed look at the state of private equity in a post-pandemic market, focusing on valuations, capital solutions and restructuring opportunities. We then take a detailed look at the forward momentum of the U.S. financing markets, the telehealth investment landscape, the use of long-hold investment strategies, and the risks and rewards associated with IP in tech deals. For a global perspective, we provide updates on the UK Listings Review, the new tax regime for UK holding companies and the Asia private equity market.

We also share insights on how the new U.S. administration may impact the business and regulatory climate. For more information about this topic, we encourage you to visit Ropes & Gray's Capital Insights microsite (click the tile below).

We hope you find this issue timely, engaging and informative. As always, we encourage you to reach out to your Ropes & Gray team (or to the authors noted herein) with any questions regarding this newsletter or any other legal developments of interest to you. We look forward to seeing you in person again soon—until then, stay well.

Visit our **Capital Insights microsite** for the latest updates

CLICK HERE

IN THIS ISSUE

LAW360

"PRACTICE GROUP OF THE YEAR"

Private Equity ▪ Fund Formation ▪ Healthcare

(PE 2017-2020; FF 2019; HC 2019-2020)

Only firm named "Practice Group of the Year" for private equity, fund formation and healthcare in 2019 (and private equity and healthcare in 2020)

PE MARKET UPDATE

Private Equity in a Post-Pandemic Market

Private equity (PE) firms may have weathered the worst of the pandemic to date, but the impact of COVID-19 will continue to shape valuations and capital structures and may bring new restructuring opportunities.

DESPITE A TUMULTUOUS YEAR, the PE sector in the United States came through 2020 in relatively robust shape, leaving it well prepared to pursue growth opportunities in 2021. Even though global buyout and exit deal value fell by approximately 30% and 60%, respectively, in Q2 2020—as lockdown measures were being imposed across much of the globe and entire sectors were effectively shut down in the process—PE dealmaking rebounded to end 2020 on a high.[1]

Boosted by an estimated US$2.5 trillion in dry powder to invest, global buyout deal value climbed 3.3% from US$589 billion in 2019 to US$608.7 billion in 2020, according to data from Mergermarket.[2] Buyout volumes were only marginally down year-on-year, falling from 3,789 deals to 3,509 transactions.[3] Exit deal value rose 5.3% year-on-year to US$555.1 billion—despite the fact that deal count fell by 17% during the same period.[4] The rise in PE transaction value stands in contrast to a 6.6% annual decline in overall global M&A value, illustrating the resilience of the asset class.[5] PE sponsors were bidders in more than a quarter of all M&A deals globally, the highest annual figure on Mergermarket record.

"M&A activity came back pretty well in the second half of the year, as PE dealmakers adjusted to doing deals in a different way," says **KIRAN SHARMA**, a PE partner at Ropes & Gray in London. "Deals for good assets that spoke to the market continued to be done. If anything, because there were fewer deals, there was a much more competitive marketplace, which pushed overall deal value even higher."

That resilience means the asset class is in a strong position for deal-making. A number of deals that were put on hold because of COVID-19 are expected to come back to market, and firms that paused to focus on portfolio management in the first stages of the pandemic have been moving actively to get their deployment schedules back on track. Buyout firms, meanwhile, are expected to continue setting the bar high for deal targets. Through the pandemic, PE dealmakers have clustered around assets that provide downside risk protection as well as growth potential.

As a result, buyout activity has skewed toward deals in the technology, life sciences and healthcare sectors. PE firms did 913 technology deals worth US$158.7 billion in 2020, up from 845 deals worth US$117.8 billion in 2019, according to Mergermarket data. The 436 life sciences and healthcare deals (including pharma, medical and biotech deals) were valued at US$70.6 billion, and also surpassed 2019 volume figures (374 deals).[6]

VALUATIONS HOLD FIRM

THIS FOCUS ON STABLE BUSINESSES in resilient sectors is expected to remain a theme in what is still an uncertain macroeconomic environment. At the same time, the appetite for quality assets among PE firms is forcing buyout dealmakers to achieve higher valuations in order to secure transactions despite wider economic dislocation.

Expectations that valuations would fall due to the pandemic have not materialized, with median EBITDA multiples for buyouts standing at 12.1x in 2020, in line with the previous year's multiples.[7] The market has, however, bifurcated between high-quality businesses in desirable sectors and those in more challenging industries hit particularly hard by the pandemic, such as travel, hospitality and leisure, as well as physical retail. In desirable sectors, such as technology and business services, PE investors have continued to pay median EBITDA multiples of 16x and 14.3x, respectively.[8]

"COVID-19 had an uneven impact on different industries," says **PENG YU**, a Ropes & Gray PE partner based in Hong Kong. "Certain industries, particularly TMT and healthcare, have done very well during the pandemic. Valuations for some of the companies in these industries are at record highs."

CHAU LE, a Ropes & Gray PE partner based in San Francisco, adds that there has been "a huge shake-up in terms of what is considered valuable and what is not. A big event like COVID-19 changes the way our world looks and feels. Businesses that weren't receiving much attention suddenly turned out to be crucial in a post-pandemic world, and you saw valuations change to reflect that."

For example, companies with a focus on remote learning suddenly found themselves in the spotlight as schools around the world went virtual. Similarly, telehealth systems that were of moderate interest pre-pandemic have taken on far greater importance as people continue to seek medical attention remotely.

Buyers, meanwhile, have taken steps to build comfort when acquiring assets at full price by assessing a target's earnings over a longer time period and undertaking a deeper analysis of how a business has steered through pandemic disruption.

Larger vendor and management team rollovers, as well as earnouts, were used to nudge buyers to close during the first round of lockdowns, but as activity levels have recovered, it has been easier for vendors to sell assets at high prices without having to take such measures.

"In March and April 2020, you saw more creativity around how to price assets, and we saw the use of earnouts and similar structures," says New York-based Ropes & Gray PE partner **SCOTT ABRAMOWITZ**. "But toward the end of the year, it felt like buyer concerns went away. From an M&A perspective, it felt like we were right back to where we were at the beginning of the year."

CAPITAL STRUCTURES STRETCHED

STRONG DEAL ACTIVITY, however, does not mean that PE portfolio companies are in the clear. Many businesses are still grappling with reduced earnings and uncertainty around future growth, prompting ongoing discussions with lenders around amending capital structures. This is expected to remain a trend in the market, even as vaccine programs are rolled out and economies reopen.

FOCUS ON FINANCE

U.S. Financing Markets – Forward Momentum

- Positive sentiment driven by the announcement of COVID-19 vaccine approvals buoyed the institutional markets in late 2020.
- After pausing in early November for the U.S. elections, activity resumed and has continued at a brisk pace into 2021, with repricings increasingly common as demand remains elevated (in some cases, despite the applicability of 1% soft call premiums).
- The high yield market remained red hot and hit an annual volume record of $435 billion for 2020.
- The institutional loan markets in Q4 maintained the elevated primary levels first seen in Q3, with supply increasingly driven by the recent uptick in M&A activity, and prices in the secondary market have rallied to return to approximately pre-COVID levels; nevertheless, annual volume ($288 billion) in 2020 was down 7% from 2019, largely driven by the slowdown in Q2.
- In a sign of resurgent investor appetite, the syndicated second lien loan market has again become attractive to borrowers (in lieu of privately placed second lien loans).
- Overall, credit documentation terms have started to resemble those from the early 2020 pre-COVID era.
- On the other hand, companies in sectors particularly negatively affected by COVID-19 that obtained financial covenant relief in 2020 may require an extension later into 2021.

"The liquidity issues that companies face remain, and the residual impacts of the pandemic will probably continue for some time," says Boston-based Ropes & Gray finance and capital solutions partner **ALYSON GAL**. "Pandemic shutdowns are still with us, and modifications to suspend financial covenants and amortization are very much factors, as are establishing liquidity tests in lieu of financial covenants."

LEONARD KLINGBAUM, a partner in Ropes & Gray's finance group in New York, adds that the "overwhelming ask has been that there be liquidity covenants as opposed to relying strictly on leverage or other EBITDA-related covenants" in new deals and where current terms have been amended.

"I think there's a growing recognition that certain financial covenants—especially with adjusted EBITDA and add-backs—do not necessarily provide a true picture of a company's situation," says Klingbaum. "We have also seen shorter maturity dates, which allow lenders to revisit situations as the pandemic unfolds."

When PE firms have required more headroom from investors, however, banks and private lenders have been willing to provide flexibility to see credits through.

"Governments around the world have leaned on banks quite heavily to support businesses, rather than pull the plug," says **SAMUEL NORRIS**, a partner in Ropes & Gray's capital solutions and finance group in London. "Following the financial crisis, lenders realized that aggressive strategies aren't always effective and a more collaborative approach to stressed and distressed situations can yield a better outcome. Sponsors have also tightened 'white lists' over the years and exercised more control over who comes into their debt. The result is that loan-to-own strategies are harder—or need to be more creative."

DISTRESS DELAY

THE WILLINGNESS ACROSS THE LENDER COMMUNITY to amend and extend terms, as well as government financial support measures and a moratorium on creditor enforcement, have helped PE firms nurse portfolio companies through the crisis.

"There has been a lot of kicking the can down the road," says New York-based Ropes & Gray restructuring partner **CRISTINE PIRRO SCHWARZMAN**. "Rather than extending terms for the usual quarter or six weeks, we have seen borrowers successfully negotiate extensions of up to two years."

With borrowers able to buy more time, restructuring activity has oscillated through the year, and restructuring volumes have been lower than anticipated, given the scale of COVID-19's impact on businesses.

"The COVID-19 environment has been characterized by radical swings in restructuring activity," says New York-based Ropes & Gray restructuring partner **RYAN PRESTON DAHL**. "Late Q1 and Q2 2020 saw a tremendous upswing in the volume and velocity of corporate restructurings. But this activity has subsided to a significant degree as we continue to see almost unprecedented levels of liquidity being injected into the market from private, public and quasi-public investors, as well as an ever-increasing risk appetite for investors chasing yield."

As lockdown restrictions are lifted and government support measures are wound down, more clarity will emerge around which companies are sustainable in a post-COVID-19 world.

"There will come a time when a lot of businesses will have to acknowledge that they are not going to return to 2019 numbers for a couple of years, and that they are going to have to restructure to reflect that. It's going to get a lot more active from a restructuring point of view as the year progresses," says London-based Ropes & Gray restructuring partner **MATTHEW CZYZYK**.

Whether restructuring or pursuing new deals, PE dealmakers are facing a busy year ahead. ■

CAPITAL INSIGHTS

Perspectives on the New Administration

In this feature, partners from various practice groups share their insights on how the new administration may impact the business and regulatory climate.

Private Equity

"The new administration's potential impact on the governmental and regulatory environment for the private equity industry is clearly a focal point," said partner **Neill Jakobe**. "I think this focus is heightened following the extensive government relief programs being implemented in response to the COVID-19 crisis and a sense that regulatory enforcement activity is picking up."

Asset Management

"The list of 2021 priorities for the SEC's newly named Division of Examinations is expansive—also because a new SEC chair has been named—but fund boards can still take clues from the release of a 42-page book that broadly covers several areas," said partner **Paulita Pike**. "At a time of transition such as now, covering more rather than less allows for the agency to focus and prioritize down the road and be flexible along the way. That's exactly what you want."

Healthcare & Life Sciences

"At some point, the plans will have to look at where telehealth goes in terms of reimbursement and how that develops, whether as part of a fee-for-service or part of a capitated structure or other risk arrangement," said partner **Timothy McCrystal**.

"President Biden is wasting no time taking steps to bolster protections under the Affordable Care Act, including increasing the level of premium subsidies and extending the open enrollment period. Efforts also include expanding Medicaid to cover a larger percentage of lower-income adults, as well as freezing a number of the prior administration's reforms involving drug pricing," said partner **Michael Beauvais**. "We are seeing companies that focus on these subsectors attract significant interest from investors."

Capital Markets

"If you look at the significant flow of transactions, there has to be a limit at some point on investor capital and to the number of available targets," said partner **Paul Tropp**. "I don't think that we're at that point yet. There's still a sense that there are a meaningful amount of targets for SPACs."

Litigation & Enforcement

"Presuming the Biden administration engages more proactively globally than the Trump administration, we can expect to see more international coordination and cooperation," said partner **Ryan Rohlfsen**. "Hopefully, we will also see coordination in resolutions to give companies greater transparency and clarity around multijurisdictional enforcement actions."

ESG

"The private equity industry has been working to adapt ESG diligence review processes and ESG-related fund marketing materials to comply with the DOL's final ESG regulation," said partner **Joshua Lichtenstein**. "In March 2021, the Biden administration's DOL provided a respite from these requirements when it announced that it will not enforce the rule until it finishes reevaluating it."

"The Biden administration will likely push to standardize and structure ESG disclosure," said partner **Michael Littenberg**. "Since the term 'ESG' is loosely defined, fund managers should be clear in their disclosures about which elements of ESG they're taking into account and how they screen for such factors."

Data, Privacy & Cybersecurity

"The new administration may be able to build on recent momentum to sway companies to report data breaches that do not involve personal data. Nothing would work faster than articulating a new policy giving companies safe harbors or liability protections for information sharing," said partner **Edward McNicholas**. "The administration will need to have a clear set of rules and standards if it hopes to persuade companies to freely supply it information." ■

GLOBAL MARKETS OUTLOOK

UK LISTINGS REVIEW
Overdue Commitment to London Financial Markets

EVEN FOR BREXIT SCEPTICS, a long-held hope was that the UK's exit from the EU would pave the way for a reform of the UK financial markets. Over the past few years, a number of growth companies (including tech and life sciences companies) and SPACs have opted for the more flexible U.S. listing regimes over the London Stock Exchange.

The current differences between the U.S. and the UK are stark—whilst 2020 saw a U.S. SPAC boom (c. $80 billion in proceeds raised from over 200 IPOs, with the pace accelerating in Q1 2021), £30 million was raised in the UK in the same period. In addition, Amsterdam is now looking to establish itself as the European hub for SPACs—ESG Core Investments was the first SPAC listing of 2021 on Euronext Amsterdam, but there are many more in the pipeline.

"Instances like fashion retailer Farfetch choosing New York for its IPO rather than its home jurisdiction of the UK were felt keenly in the UK," said Ropes & Gray London PE partner **ELIZABETH TODD**. "If the UK can close the gap between its regulatory regime and other global centers, it will become much more competitive as a listing destination."

The UK Listings Review, launched by UK Chancellor Rishi Sunak and led by Lord Hill, was published on 3 March 2021. The Review has recommended:

- Modernizing the UK's listing rules to allow dual-class share structures in the London Stock Exchange's (LSE) premium listing segment (which would allow founders to have enhanced voting rights on certain decisions but still trade on the most liquid exchange).
- Reducing free-float requirements from 25% to 15%.
- Liberalizing rules regarding SPACs, including removing a requirement for trading in SPAC shares to be suspended at the point an acquisition is announced (currently, investors are locked in even if they do not approve of the potential purchase; this has dampened investor appetite for SPACs subject to UK rules).
- That the Chancellor report annually on the competitive position of the City of London (which would be a natural prompt for further improvements).
- A fundamental review and reform of the prospectus regime, including treating admissions and offers to the public separately, with an aim of drastic simplification and increased flexibility.

"Even just the publication of the report seems to have had an effect," said Todd. "Food delivery company Deliveroo chose London as the venue for its $7.59 billion IPO, focused on the fact that its dual-class structure aligned with the findings of the Lord Hill review on the benefits of allowing founders to keep more control."[9]

Some investor organizations have, however, urged the government to be cautious with any changes, noting that a balance will need to be struck between protections for investors (particularly retail investors) and flexibility for issuers.

The UK government has committed to move quickly to act on the recommendations, so we expect next steps shortly, with public consultation on legal and regulatory changes to commence within the next couple months. ■

Author: Elizabeth Todd

GLOBAL MARKETS OUTLOOK

ASIA PE MARKET TRENDS 2021

2020 SAW A STAGGERED RECOVERY from COVID-19 across Asia. Deal flow dropped and bounced back higher. According to provisional data from *AVCJ Research*, despite a record-low Q1, the total PE capital deployed in 2020 totalled $198.5 billion, 17% higher than in 2019.[10]

Overall, growth capital investments in the technology space remained center stage among PE deals in 2020,[11] and investments in the healthcare sector showed strong growth, given the untapped demand in the region, the cultural shift following the pandemic and exit success stories.[12] Investors also saw control deals (including several auction processes) rebound in late 2020, a trend that may continue in 2021.[13]

The Asia market has been resilient in the face of geopolitical tension in 2020. According to *Asia Private Equity Review*, in a year mired in China-U.S. frictions, China-focused GPs secured undiminished interests from U.S.-based institutions,[14] and China became the top destination receiving foreign direct investments, surpassing the U.S. for the first time.[15] A pattern of "regionalization" also emerged, with China, Japan and South Korea funds actively investing in Asia outside their home markets.[16] Fundraising for pan-regional strategies, China VC funds and Japan funds showed year-on-year increase in 2020, but there was a general decline of 16% for the total amount raised in Asia.[17] Investors congregated to established GPs for perceived quality, as travel restrictions hindered diligence efforts.[18]

It remains to be seen how the new U.S. administration may affect the PE market in Asia. And with the global economy expecting an uptick in activity post-vaccine, the atmosphere among investors is tentatively optimistic. ■

Authors: Peng Yu; Oliver Nip; Leon Huang

HEALTHCARE CORNER

Talking Telehealth: Shaping Your Investment Strategy

RECAP FROM R&G VIRTUAL DISCUSSION PANEL ▪ NOV. 2020

As the global pandemic has forced cities, states and countries to embrace new ways of doing things, services such as telehealth have come into the spotlight. Even before the pandemic, telehealth was attracting investor interest. Over the past year, PE firms and strategic investors have stepped up their evaluations of this burgeoning sector.

Our panel of industry leaders comprised of investors, payors, providers and legal advisers examined the outlook for telehealth. Here are some of their observations:

PERSPECTIVES ON THE ROLE OF TELEHEALTH & THE DELIVERY OF HEALTHCARE

- Because of COVID, we've accelerated the use of telehealth by years. In many ways, there's no turning back. Providers have embraced telehealth, and by extension, patients are more accepting.
- As we come out of the pandemic, we'll get better data on whether telehealth is a substitute [for in-person office visits] or an addition. It's possible that telehealth will replace the need for general health visits, along with prescription refills and even some high-level diagnoses.
- Some specialties, such as behavioral health, will be faster to adapt. You've also got demographic factors—younger generations are much more comfortable with telehealth.

Value-based care is essential.
We need to ensure we're not increasing total medical expenses (e.g., readmission to a hospital for the same diagnosis).

- There will also be regulatory hurdles. We have 50 states, each with its own priorities, which could make it difficult to scale nationwide.

KEY REIMBURSEMENT CONSIDERATIONS

- Some states want payment parity for a telehealth visit and an in-person office visit, but forcing reimbursement parity may not lower medical expenses.

- Value-based care is essential. We need to ensure we're not increasing total medical expenses (e.g., readmission to a hospital for the same diagnosis).

- If you're able to get providers in front of chronic populations, that's where you have an opportunity to cut costs, because right now they're not being treated at all. The extent to which we can drive preventive care will determine appropriate reimbursement levels.

KEY CHALLENGES IN INVESTING IN NEW SERVICES

- The challenge for investors is determining valuations and questioning whether gross margins are tracking to be valued like a technology business. Right now, the long-term economic or margin profile for these businesses remains unclear.

- We're still in the early innings of using technology to manage patients, improve provider efficiency and drive down costs, but there is an opportunity to fix demand/supply imbalances and create value within the provider landscape.

- On regulation, states need to be more flexible about exchanging information, allowing doctors across lines, etc. On privacy, there will be some rollbacks. The key will be what they will do on enforcement, and what providers will do on compliance.

ACCESS TO TELEHEALTH

- Technology is important in expanding access to telehealth within certain communities and parts of the country.

- The challenge coming out of COVID is that we're likely to see rollbacks (e.g., HIPAA and privacy considerations). Folks in rural areas who don't have access to broadband may need to go to clinics because services aren't reimbursable.

- We may see payors become more willing to invest in infrastructure and partner with companies to help broaden access in rural areas and underserved communities.

COST SAVINGS TO THE HEALTHCARE SYSTEM

- Pre-COVID, there was no real data. Since COVID began, some payors have committed to reimbursing telehealth at the same level as an office visit, but these concessions may not be sustainable.
- One area to focus on is remote patient monitoring for chronic care conditions. Some payors want to see savings before they're willing to pay, so it's a value-based care model where you have to hit certain savings thresholds to get paid. For certain high-cost populations, technology can be beneficial.
- There is at least a three- to four-year lag in value-based arrangements, including in reimbursement models. We need a partnership between providers and payors to test these models. That's an iterative process.

THE PATH FORWARD

- One of the key barriers to the adoption of telehealth prior to COVID was provider reluctance. COVID has gotten providers more comfortable with telehealth. This shift should allow telehealth to be maintained post-COVID at much higher levels than before.

- We may see more traction four or five years down the road as providers understand how best to manage high-cost groups with chronic conditions through telehealth. ■

ASSET MANAGEMENT ANGLE

Using Long-Hold Investing as a Competitive Advantage

IN A HIGHLY COMPETITIVE transactional environment, price is key to winning attractive investment opportunities when competing against other financial buyers and has historically been the most important factor where PE buyers compete with strategic and other potential suitors. For some investment targets, such as family- or founder-owned businesses, however, an offer from a buyer with a long-term investment horizon can sweeten an otherwise comparable pricing offer and, in some circumstances, outweigh better pricing (at least within reason).

The traditional PE model, including its structural incentives, is not well suited to long-duration investing. The traditional 10-year fund term drives PE sponsors to holding periods that are often much shorter than sellers want, particularly for investments that are acquired later in a fund's investment period. While the power of the carried interest model as a value maximization incentive is not lost on sellers, this incentive drives PE buyers to maximize value during the holding period, which may—but does not necessarily—align with value maximization on a long-term basis. These factors can lead to a cycle of repeat sales among PE firms every three to five years, which can create inherent frictions and costs of ownership transfer.

TAX TIME

A New, Improved Tax Regime for UK Holding Companies

HMRC has launched a second-stage consultation on the tax treatment of UK holding companies in fund structures. The UK already has an attractive regime for equity investments that is widely used for UK transactions and for some international transactions. However, there are some drawbacks to the current UK regime, particularly for debt investments or investments including a combination of debt and equity.

Recent changes following the OECD's BEPS project have also led a number of managers to pursue a strategy of making investments through a master holding company, often in the same jurisdiction as the main fund vehicle. The combination of these and other factors has led a number of UK-based managers to prefer to structure funds and investments through non-UK vehicles in jurisdictions such as Luxembourg, Ireland and the Netherlands, and to expand their operations in those jurisdictions.

The consultation seeks to promote the use of UK vehicles by establishing a special regime for "asset holding companies." The regime would apply in the context of widely held fund structures—and so apply to most, but not all, structures that UK fund managers might establish. Ambitiously, it would apply across asset classes, with UK real estate being the only real exception. Given the increasing focus on substance in the tax world, the use of UK vehicles by managers that have their main European operations in the UK is a natural fit.

The regime envisaged in the consultation—no tax on capital gains, no tax on dividends, deductibility for results-dependent interest, no withholding tax, no stamp duty, predictable transfer pricing, treaty qualification—sounds extremely attractive. Asset holding companies will pay "no more tax than is commensurate with their intermediate role in the fund structure."

However, the consultation document also expresses reservations about the risk that such a regime could be used for tax avoidance. This creates cause for concern that the regime will be excessively complicated. The UK certainly has form for this.

If HMRC is able to curb this tendency to complexity, this is a well-timed and well-directed consultation that could result in an attractive and user-friendly regime that will significantly help to support the attractiveness of the UK as a hub for asset management. ■

Authors: Brenda A. Coleman; Andrew Howard

These considerations can drive sellers to favorably view non-PE buyers that offer a longer-term solution and reduced likelihood of resale between PE sponsors. For example, large family offices, sovereign wealth funds and similar single-investor-backed investment vehicles can serve as alternatives to PE funds while avoiding the holding period constraints of the traditional PE fund model. To address these limitations, some PE sponsors have abandoned the traditional finite-term fund model in favor of long-dated or permanent capital vehicles that permit extended or indefinite holding periods, though this remains a small subsection of the market overall.

For the vast majority of PE firms that remain committed to the traditional finite-term fund paradigm, it is worth considering options to incrementally change the classic PE model in ways that help satisfy desires for a longer-term investment horizon and better allow funds to compete on grounds other than price. Unlike more dramatic shifts to long-dated, permanent capital and similar models, these changes can be done without major structural changes for the PE firm itself or for its core investors. For example, the simplest change can involve lengthening the fund's term. Approximately one-third of recent PE funds either have base terms exceeding 10 years or are pre-wired to allow sponsors to unilaterally extend the term beyond 10 years. Though relatively easy to implement, this change doesn't fully address—and only marginally extends—the limited duration of the classic private fund model.

On the other hand, the proliferation of GP-led secondary transactions, including single-asset transactions, indicates the growing acceptance of longer-term ownership of high-performing assets by a single sponsor. GP-led secondaries permit continuity of sponsorship to be retained substantially longer than the term of the original fund through the sale of a portfolio company from an existing fund to a new vehicle with a different time horizon. Since these vehicles are created with a specific company or companies in mind, the time horizon can be directly shaped to the circumstances of the relevant company.

However, such transactions can be complicated and raise conflicts of interest and other investor-driven and regulatory considerations. They also represent an inherently back-ended solution to the long-term hold issue. Because sponsors cannot make a commitment to undertake a GP-led secondary at the time of initial investment in a portfolio company, the prospect of such a transaction offers relatively little comfort of long-term partnership to target company sellers. Nevertheless, sponsors raising new funds can augment contractual provisions and disclosures designed to facilitate these transactions at the time of fundraising, which can both lessen the approvals required to undertake such transactions and signal intent to prospective portfolio companies.

In some ways, the most noteworthy recent development regarding long-hold structures is the incorporation by a few sponsors of flexibility to extend ownership within the traditional fund structure. By pre-wiring long-hold, continuation vehicle-type structures into their fund agreements, these sponsors maintain flexibility over how assets are held while offering a more compelling and credible long-term offering to target company sellers from the outset. These sponsors also avoid having to employ both dedicated traditional and long-hold structures and, as a result, are positioned to make decisions over time as to the right approach to realization timing on a portfolio company by portfolio company basis.

The nature and extent to which sponsors can change their fund terms will depend on internal and external factors, including the preferences of key investors. However, as longer duration investing continues to grow in popularity and buyers without the constraints of the traditional PE model grow in prominence, PE sponsors may want to consider whether to seek additional flexibility that will help them compete for some of the most promising assets available in the market other than on the basis of price. ■

Authors: Arthur A. Andersen III; John B. Ayer

SPOTLIGHT ON TECH

Intellectual Property in Tech Deals: Risks and Rewards

TECHNOLOGY remains at the center of many private equity transactions—whether involving an investment in an emerging-technology company or one in a more traditional industrial company utilizing a unique technological differentiator in its products and processes. This appetite for technology deals and differentiating technology seems unlikely to wane any time soon. But as this type of investment activity remains competitive, private equity sponsors should continue to remain diligent in protecting against IP risk while also being open to new opportunities for increasing the value of an investment through the strategic use of IP.

VALUABLE TECHNOLOGY IS OFTEN TARGETED IN IP SUITS

In cases where technology provides value and a competitive advantage for an acquired portfolio company, that technology becomes an attractive target for both competitors and IP holders who may see a financial opportunity. One study highlighted how patent assertion entities were targeting companies specifically around the time of their IPO. Moreover, in the past few years, litigation funding has become a major force, funding lawsuits that previously might never have been brought, because litigation (especially patent litigation) is inherently risky and is often expensive and time consuming. But with a large amount of capital being deployed by funders on a regular basis, the potential for more IP-centered lawsuits is real. Indeed, the price for patents on the secondary market has been increasing as U.S. federal courts have become less willing to dismiss patent suits at the early stages of a case. For private equity sponsors, this technology litigation risk has led to cases where they have actually been named as defendants, with opportunistic plaintiffs seemingly chasing dollar signs up the ownership chain.

So where does this leave a sponsor considering a technology-based deal? Of course, traditional diligence should continue to be conducted to identify any lack of adequate IP protection for the target's own products, as well as to consider whether any competitors present a high litigation risk (based on their own IP holdings and/or their willingness to litigate in the past). But sponsors should also have a plan in place to quickly assess and deal with any IP risks that are harder to identify and quantify—especially from non-competitors, including non-practicing entities, who may be emboldened with new access to litigation capital and view a recently acquired technology company as a prime target. This plan should include, at least:

- Quickly assessing risk and developing substantive defenses (subjective belief of non-infringement and/or invalidity can help defend against a later allegation of willful infringement).

> **Significant value** can come from a company's IP assets, which often sit unused (or exist in a less-than-optimal, unmanaged state)—so-called Rembrandts in the attic.

- Taking "patent troll letters" seriously, as seemingly insignificant patents/patent holders may now be backed by more significant sources of funding.
- Considering whether strategic licensing can reduce risk, including through amendment, renegotiation or termination of existing agreements.
- For portfolio companies with key product lines that are vulnerable to being attacked by a competitor, looking for areas where patent protection (or trade secret protection) could be strengthened, particularly surrounding differentiating features, and investigating whether any competitor patents could be vulnerable to preemptive challenge at the U.S. Patent Office's Patent Trial and Appeal Board ("PTAB").

TECHNOLOGY CAN ALSO PROVIDE A REAL OPPORTUNITY FOR UNLOCKING ADDITIONAL VALUE

Certainly not all technology deals involve only risk avoidance. In fact, beyond protecting a company's key products or processes, significant value can come from a company's IP assets, which often sit unused (or exist in a less-than-optimal, unmanaged state)—so-called Rembrandts in the attic.

An important first step is understanding what IP assets a portfolio company has, the scope of those assets and their importance to the relevant industry, and how they have been maintained. Have appropriate patents been obtained? Has the company obtained protection in key foreign geographies? Does competitive intelligence indicate that other companies might be infringing any of these patents? And if so, how easy is infringement to prove using public information? Are there pending applications that might soon issue as valuable patents that can be asserted strategically? Do those pending applications include disclosures that would allow a new, more strategic set of patent claims to be pursued? Has this portfolio company relied heavily on trade secrets to maintain a competitive advantage in the marketplace—and if so, how strongly has it protected such secrets?

In an ideal scenario, once potentially valuable IP assets have been identified, a subset could be asserted against a vulnerable competitor, through either licensing or litigation, to increase market share, secure a monopoly right for a key product or feature, and/or generate revenue based on the use of that IP. One example might be to identify IP directed to a differentiating product feature, and then assert that IP against competitors to prevent them from mimicking that feature. Additionally, IP could be licensed to an adjacent industry, allowing for an additional revenue stream that does not compete or conflict with revenue from the company's patent-protected product. But even if a portfolio company does not have the right IP assets in place to clear out a competitor through an affirmative patent assertion, that company may instead determine that a key competitor has vulnerable patents of its own that could be attacked in the PTAB to clear the way for a new or existing competitive product.

IP assets are often underutilized and can ultimately provide value to a portfolio company (and its sponsor) in a variety of ways, depending on the scope of coverage, dynamics of the particular industry in which the company operates, and the willingness of the portfolio company to take opportunities to create value from otherwise dormant assets. ■

Author: Kevin J. Post

END NOTES

[1] Mergermarket Global & Regional M&A Report 2020 Including League Tables of Financial Advisors. *See pages 10-11.*
[2] https://www.bain.com/insights/the-2-5-trillion-question-podcast/.
[3] Mergermarket Financial League Table Report. Q4 2020. *See page 10.*
[4] Ibid. *See page 11.*
[5] Ibid. *See page 4.*
[6] Ibid. *See page 5.*
[7] Ibid. *See page 5.*
[8] Ibid. *See page 12.*
[9] A poor first day of trading on 31 March 2021 (shares down 31% at the time of writing) has led commentators to question whether this was the right decision.
[10] Tim Burroughs, "4Q Analysis: Growth Spurt," *AVCJ* (Jan. 22, 2021), https://www.avcj.com/avcj/analysis/3022530/4q-analysis-growth-spurt.
[11] *Id.*
[12] Tim Burroughs, "2020 in Review: Surprise Guest," *AVCJ* (Dec. 17, 2020), https://www.avcj.com/avcj/analysis/3022212/2020-in-review-surprise-guest.
[13] Tim Burroughs, "Buyouts in 2021: Winners and Losers," *AVCJ* (Jan. 13, 2021), https://www.avcj.com/avcj/analysis/3022413/buyouts-in-2021-winners-and-losers.
[14] "Pivot in Asia," *Asia Private Equity Review*, Dec. 2020 at 19.
[15] Paul Hannon & Eun-Young Jeong, "China Overtakes U.S. as World's Leading Destination for Foreign Direct Investment," *The Wall Street Journal* (Jan. 24, 2021), https://www.wsj.com/articles/china-overtakes-u-s-as-worlds-leading-destination-for-foreign-direct-investment-11611511200.
[16] "Playbook Revised," *Asia Private Equity Review*, Dec. 2020 at 7.
[17] Tim Burroughs, "4Q Analysis: Growth Spurt," *AVCJ* (Jan. 22, 2021), https://www.avcj.com/avcj/analysis/3022530/4q-analysis-growth-spurt.
[18] *Id.*

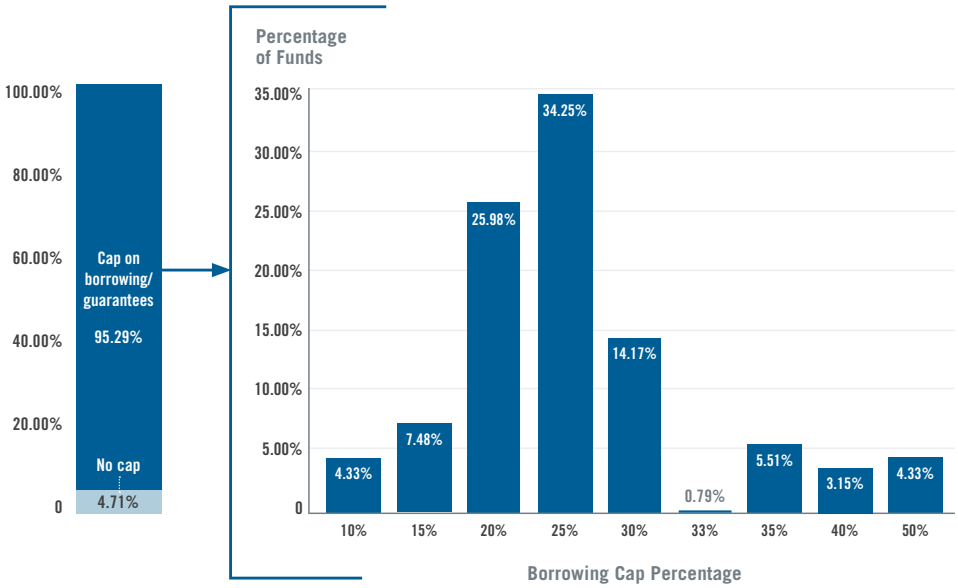
MARKET WATCH

We collect data from private investment funds to enter into our proprietary database, which contains information and analytics on fund terms from more than 3,500 buyout, credit, venture capital, growth equity and infrastructure funds.

The charts represent data on borrowing for buyout funds vintage 2016 through 2021. The overwhelming majority of funds have a cap on borrowing, and the cap typically ranges from 20% to 30% of commitments. Further, the data shows that most funds include both guarantees and capital call facility borrowing when calculating the overall cap.

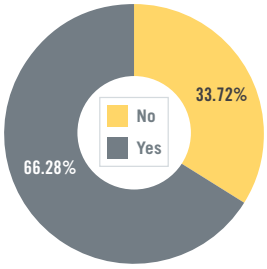
Our access to market and industry insights at a granular level gives sponsors the advantage of unsurpassed visibility into the private equity fund landscape, along with the valuable acumen needed to stay a step ahead.

LIMIT ON OUTSTANDING BORROWING/GUARANTEES

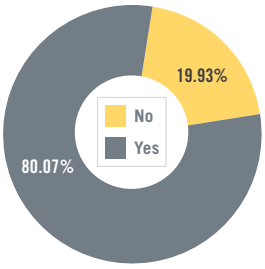


BORROWING CAP DETAILS

Are Guarantees Counted Toward the Borrowing Cap?



Is Capital Call Facility Borrowing Counted Toward the Cap?



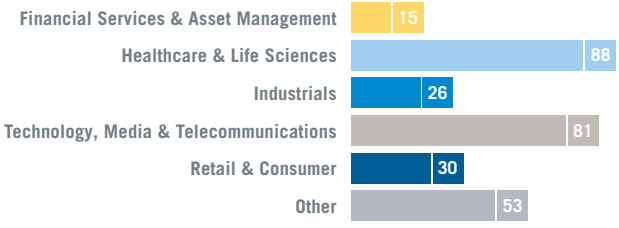
PE BY THE NUMBERS

A Global Private Equity Transactions Practice
Since Jan. 1, 2020 (announced PE-related transactions)

293 Deals

$240+ Billion in transactions

19 Countries



NOTABLE FUNDRAISES

Represented **AlpInvest Partners** in the formation of AlpInvest Secondaries Program VII, which closed at $9 billion

Represented **Antares Capital** in the formation of its first Senior Loan Fund, which closed with $3 billion of purchasing power

Represented **ArcLight Capital Partners** in the formation of ArcLight Energy Partners Fund VII, which closed at $3.4 billion

Represented **B Capital Group** in the formation of its second fund, which closed at $820 million

Represented **BV Investment Partners** in the formation of Fund X, which closed at $1.1 billion

Represented **Constitution Capital Partners** in the formation of Ironsides V, which closed at $1 billion

Represented **Cowen** in the formation of Cowen Healthcare Investments III, which closed at $493 million

Represented **Cyprium Partners** in the formation of its fifth fund, which closed at $445 million

Represented **Gauge Capital** in the formation of Gauge Capital III, which closed at $800 million

Represented **Gridiron Capital** in the formation of Gridiron Capital Fund IV, which closed at $1.35 billion

Represented **Hamilton Lane** in the formation of Hamilton Lane Secondary Fund V, which closed at $3.9 billion

Represented **Index Ventures** in a $2 billion fundraise across two funds, Index Ventures Growth V and Index Ventures X

Represented **Kohlberg & Company** in the formation of Kohlberg Investors IX, which closed at $3.4 billion

Represented **LongRange Capital** in the formation of its inaugural fund, which closed at $1.5 billion

Represented **Manulife Investment Management** in the formation of Manulife Private Equity Partners, which closed at $1.5 billion

Represented **Neuberger Berman** in the formation of NB Strategic Co-Investment Partners IV, which closed at $2.1 billion

Represented **Oberland Capital** in the formation of Oberland Capital Healthcare Solutions Fund, which closed at $1.05 billion

Represented **Pacific Equity Partners** in the formation of PEP Fund VI, which closed at AUD$2.5 billion (US$1.79 billion)

Represented **Sculptor Capital Management** in the formation of Sculptor Real Estate Fund IV, which closed at $2.6 billion

Represented **Shoreline Equity Partners** in the formation of Shoreline Equity Partners Fund, which closed at $300 million

Represented **Siguler Guff** in the formation of Small Buyout Opportunities Fund IV, which closed at $1.575 billion

Represented **Thomas H. Lee Partners** in the formation of THL Automation Fund, which closed at $900 million

Represented **The Vistria Group** in the formation of Vistria Fund III, which closed at $1.11 billion

Represented **Welsh, Carson, Anderson & Stowe** in the formation of a joint venture with Humana's Partners in Primary Care

Represented **Wynnchurch Capital** in the formation of Wynnchurch Capital Partners V, which closed at $2.277 billion

NOTABLE TRANSACTIONS

FORESCOUT Represented **Advent International** in its acquisition of Forescout Technologies	GERBER TECHNOLOGY Representing an affiliate of **American Industrial Partners** in the pending sale of Gerber Technology to Lectra S.A.	Elm Street Technology Represented **Aquiline Capital Partners** in its investment in Elm Street Technology	BresMed Represented **Arsenal Capital Partners** in its acquisition of BresMed Health Solutions	Kofile Represented **Audax Group** in its acquisition of Kofile
XIFIN Represented **Avista Capital Partners** in its acquisition of Xifin	SHOWA AIRCRAFT INDUSTRY CO.,LTD. Represented **Bain Capital** in its acquisition of Showa Aircraft	Lumenis Energy to Healthcare Represented **Baring Private Equity Asia** in its acquisition of Lumenis	HERMES Represented **The Carlyle Group** in the sale of Hermes Transportes Blindados to affiliates of CVC Capital Partners	THE HILLMAN GROUP Represented **CCMP Capital** and the parent company of **The Hillman Group** in the merger with Landcadia Holdings III, a SPAC
kalkomey Represented **Cove Hill Partners** in its acquisition of Kalkomey Enterprises	ENVISION PHARMA GROUP Represented **GHO Capital** in its acquisition of Envision Pharma Group	Clinical Ink Confident Decisions, Faster Represented **GI Partners** in its acquisition of Clinical Ink	SMTC Represented **H.I.G. Capital** in its investment in SMTC Corporation	Galway INSURANCE Represented **Harvest Partners** in its acquisition of a majority interest in Galway Insurance Holdings
workhuman Represented **Intermediate Capital Group** in its acquisition of a minority stake in Workhuman	Cyrus O'LEARY'S Represented **Kohlberg & Company** portfolio company **Sara Lee Frozen Bakery** in the acquisition of Cyrus O'Leary's Pies®	ASTRO SHAPES Represented **Monomoy Capital Partners** in its acquisition of Astro Shapes LLC	INFRAMARK Represented **New Mountain Capital** in its acquisition of Inframark	ROVENSA Represented **Partners Group** in its acquisition of a major equity stake in Rovensa
BEACON HOSPITAL A Good Hospital Represented **TPG Capital** and its portfolio company **TE Asia Healthcare Partners** in the add-on acquisition of Beacon Hospital	DIRECTV Represented **TPG Capital** in its investment in DirecTV with AT&T	pathway vet alliance Represented **TSG Consumer Partners** in its acquisition of Pathway Vet Alliance	SCA pharma Represented **The Vistria Group** and **Excellere Partners** in the investment in SCA Pharmaceuticals	innovAge Represented **Welsh, Carson, Anderson & Stowe** in the sale of a 49% stake in InnovAge to Apax Partners

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DIGITAL HEALTH

China

LEXOLOGY
Getting The Deal Through

Digital Health

Quick reference guide enabling side-by-side comparison of local insights, including market overview; legal and regulatory framework; data protection and management; intellectual property rights, licensing and enforcement; advertising, marketing and e-commerce; payment and reimbursement; and recent trends.

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China

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MARKET OVERVIEW AND TRANSACTIONAL ISSUES

Key market players and innovations

Who are the key players active in your local digital health market and what are the most prominent areas of innovation?

Key players include:

- central Chinese government and sectoral regulators;
- private healthcare businesses, including entrepreneurs and start-up businesses, which are concentrated along the Yangtze River Economic Belt, the Greater Bay Area and the Beijing/Tianjin Area;
- insurance companies;
- healthcare professionals;
- venture capital and private equity funds; and
- academic institutions.

Key areas of innovation include internet hospitals, including telehealth and virtual health services, online pharmacy, AI-assisted patient diagnosis and patient screening, big data, and e-referral and booking capabilities. Internet hospitals are developing rapidly, driven by favourable government policy and the ongoing covid-19 pandemic. As a result, internet diagnosis and treatment and online drug purchasing have become increasingly habitual in China. Users for online consultation, medical e-commerce, health management and other platforms have also experienced significant growth over the last year.

Law stated - 30 November 2021

Investment climate

How would you describe the investment climate for digital health technologies in your jurisdiction, including any noteworthy challenges?

Digital health technologies have become a trendy investment focus of investors in the healthcare industry in China as Chinese increase their adoption of digital health technologies. The covid-19 pandemic catalysed accelerated investment in digital health and facilitated greater coordination between private and public sector participants. The healthcare space in China is in general highly regulated and shifting government policies add a layer of uncertainty to the overall investment climate.

Law stated - 30 November 2021

Recent deals

What are the most notable recent deals in the digital health sector in your jurisdiction?

Some notable recent deals in the digital health sector in China include:

- October 2021: Tencent backed Yuanxin Tech, the operator of Miaoshou Doctor, an online medical platform, filed for an IPO on Hong Kong Stock Exchange (HKEX). Previously, Yuanxin Tech had completed a series F round raising over 1.5 billion yuan from investors including Sequoia Capital China.
- September 2021: On 7 September, ByteDance invested 200 million yuan to invest in the mental health internet

medical platform, Haoxinqing, the largest domestic investment in the mental health field to date. Also, on 9 September, ByteDance's medical brand, Xiaohe Yiliao, invested an undisclosed amount in two medical companies founded by Hu Lan, Amcare Healthcare (Meizhong Yihe) and Hongda Airui, taking 17.57 per cent and 10.71 per cent ownership, respectively.

- August 2021: Zhiyun Health, China's largest provider of digital chronic disease management solutions, filed for an IPO on HKEX. Previously, Zhiyun Health had received several rounds of financings from domestic and foreign investors, including SIG, IDG, CICC Capital, and China Merchants Bank International.
- April 2021: Tencent-backed digital health platform, WeDoctor, filed for its long-awaited IPO on HKEX. WeDoctor is valued close to US$7 billion.

Law stated - 30 November 2021

Due diligence

What due diligence issues should investors address before acquiring a stake in digital health ventures?

Key due diligence issues to understand and resolve include:

- IP/Technology: ensuring that the digital health venture has sufficient ownership or rights to use the data, software, intellectual property, and technology that is key to its business. Attention should also be paid to the enforceability of the digital health venture's intellectual property.
- Data: understanding the types of data collected and held by the digital health venture, how such data is obtained and used, cross-border and third party transfers of such data, the importance of such data to its business and its competitive advantage, and compliance with the relevant data protection regulations. In particular, if it collects human genetic resources data and transports such data to a foreign entity, it is important to review its compliance with China's regulations on human genetic resources.
- Exclusivity: understanding the digital health venture's exclusive rights to its technology and intellectual property, and any non-compete and other exclusivity covenants that may constrain a digital health venture's business or growth.

- Regulatory: verifying that the digital health venture has obtained all necessary permits and licences relevant to its products and services, or has a viable pathway to obtain them.
- Privacy: ascertaining whether the digital health venture's processing of personal information of Chinese individuals is compliant with applicable data privacy laws, including review of the lawful collection or acquisition of personal information, the legal bases for processing it, privacy notices, privacy consents, cross-border and third-party transfers, and data security practices.
- Cybersecurity: understanding the digital health venture's information security practices, including whether or not it has experienced any information security or cybersecurity incidents, been the subject of regulatory investigations or complaints relating to its cybersecurity practices.

Law stated - 30 November 2021

Financing and government support

What financing structures are commonly used by digital health ventures in your jurisdiction? Are there any notable government financing or other support initiatives to promote development of the digital health space?

Venture capital and private equity funding are common sources of financing in the digital health sector and the Variable Interest Entity (VIE) structure is commonly adopted. Historically, the VIE structure came about as a 'workaround' to allow indirect investment in industries in China in which foreign investment was restricted or prohibited by the government, such as media and telecommunications. A typical VIE structure involves a Cayman company at the top, a Hong Kong intermediary at the middle and a Wholly Foreign-Owned Enterprise (WFOE) at the bottom. The WFOE usually exercises de facto control over the operations and management of a domestic PRC entity which holds the necessary permit or permits to operate in a sector in which foreign investment is restricted or prohibited. Public financing through IPOs is also on the rise. A significant number of digital health companies filed for their IPOs in 2021.

Amid the peak of covid-19 in March 2020, the Chinese government issued clear guidance supporting reimbursement of internet healthcare. The implementation of national health insurance (NHI) policy is conducive to building a stable and sustainable profit model for digital health ventures. Four months later, the State Council released a set of key tasks for the medical system, which included incorporating big data, video monitoring, facial recognition, and other new generation information technologies.

Law stated - 30 November 2021

LEGAL AND REGULATORY FRAMEWORK

Legislation

What principal legislation governs the digital health sector in your jurisdiction?

China does not have an omnibus statute governing the digital health sector. Different laws, regulations and guidelines apply depending on business and its products or services.

A digital health product that falls under the definition of a medical device under the Regulations on the Supervision and Administration of Medical Devices (Revised in 2021) (Order #739) is regulated as a medical device. The R&D, manufacturing, distribution and use of medical devices in China are governed by Order #739.

The provision of medical services by hospitals and health care professionals is governed by the Law of the People's Republic of China on Basic Medical and Health Care and the Promotion of Health . Various administrative rules governing the provision of medical services via digital means also generally apply to the digital health sector, including the Measures for the Administration of Internet Diagnosis and Treatment (for Trial Implementation) , the Measures for the Administration of Internet Hospitals (for Trial Implementation), and the Specifications for the Administration of Remote Medical Services (for Trial Implementation).

The advertising and promotion of digital health products and services are primarily governed by the Advertising Law (revised in 2021) , the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Dietary Supplements and Food for Special Medical Purposes , and the Measures for the Administration of Medical Advertisements . Restrictions on marketing practices are set out in the Anti-Monopoly Law , the Anti-Unfair Competition Law , and their related regulations.

Since the digital health sector is highly dependent on the processing of personal information, and may involve the processing of important data, which are subject to stricter regulation, China's data security and privacy laws are of great importance. The Personal Information Protection Law (PIPL) , the Cybersecurity Law, the Data Security Law

(DSL), and Biosecurity Law constitute the four pillars of China's data security and privacy governance regime applicable to the digital health sector. Additionally, the National Health and Medical Big Data Standards, Security and Service Management Measures (Trial) applies digital health companies engaging in medical data big data.

The collection, handling and export of data derived from human genetic resources (HGR) is subject to the Biosecurity Law and the Regulation on the Administration of Human Genetic Resources . These laws and regulations formalise a longstanding practice requiring that foreign-owned entities seeking access to China's HGRs can only do so through collaborations with Chinese partners.

Furthermore, as the digital health products and services often utilise or are deployed via websites, mobile APPs, or other online platforms, China's regulations on mobile APPs, e-commerce, and online platforms generally apply, including the Telecommunications Regulations , the E-Commerce Law , the Administrative Provisions on Mobile Internet Applications Information Services and the Announcement of App Security Certification Work .

Law stated - 30 November 2021

Regulatory and enforcement bodies

Which notable regulatory and enforcement bodies have jurisdiction over the digital health sector?

Various regulatory and enforcement bodies in China have jurisdiction over the digital health sector.

- The National Medical Product Administration (NMPA), under the State Administration for Market Regulation (SAMR), is the primary regulator of digital health products in China. It is tasked with granting marketing authorisations and carrying out post-approval supervision.
- At the national level, the National Health Commission (NHC), the health department under the State Council, regulates the operation of public hospitals and health care professionals.
- The SAMR regulates the advertising and promotion of digital health products.
- The National Healthcare Security Administration (NHSA) regulates centralised procurement and reimbursement of digital health products under the Chinese Basic Medical Insurance (BMI) scheme.
- The Cyberspace Administration of China (CAC) and the Ministry of Public Security (MPS) are tasked with formulating data security and privacy laws and regulations and ensuring their compliance within the scope of their respective functions.
- At the provincial, municipal and county level, local counterparts of the NMPA, SAMR, NHC, NHSA, CAC, and MPS have rulemaking and enforcement authority over their regions, subject to national laws and regulations defining the scope of their administrative authority.
- The Human Genetic Resources Administration of China (HGRAC), an administrative entity under the Ministry of Science and Technology, is the primary regulator of the collection, handling and export of China human genetic resources (HGR) and data derived from HGR.
- The Ministry of Industry and Information Technology (MIIT) and local Communications Administrations also have an important role in regulating the digital health sector. They are in charge of formulating and implementing rules governing internet content provider (ICP) licensing and record filing, which apply to digital health products and services that provide information services via the internet.

Law stated - 30 November 2021

Licensing and authorisation

What licensing and authorisation requirements and procedures apply to the provision of digital health products and services in your jurisdiction?

Digital health products, such as healthcare apps, wearables and Software as a Medical Device (SaMD), that fall under the definition of a medical device under the Medical Device Regulation (Order #739) are regulated as medical devices. Medical devices in China are classified into three categories based on the product's risk profile. All medical devices in China must be approved in prior to marketing. Class I medical devices are subject to recordation filing requirements. Class II and Class III medical devices are subject to product registration requirements. Accordingly, digital medical devices that are classified as Class II or Class III medical devices need to be registered with the NMPA or its provincial counterparts as medical devices. Clinical trial authorisation from the NMPA is required for Class III medical devices with a higher risk profile before conducting clinical trials involving such devices.

Additional requirements may apply to the provision of digital health services, especially with respect to the provision of medical services by medical and healthcare institutions. Medical institutions are required to obtain practicing licences. Medical and healthcare institutions of all types and at all levels are also required to comply with regulations for medical and healthcare institutions issued by the Ministry of Health and its local counterparts. China has a medical practice registration system for doctors, nurses and other medical and healthcare professionals.

Distributors of drugs or medical device products via the internet need to obtain a distribution permit from local Medical Product Administrations (MPAs) if they are not the marketing authorisation holders for the products. Platform enterprises who provide online transaction-related services related to healthcare need to obtain an internet pharmaceutical information services licence from local MPAs and obtain an ICP filing or licence from local Communications Administrations.

Law stated - 30 November 2021

Soft law and guidance

Is there any notable 'soft' law or guidance governing digital health?

There are a number of government and regulatory policy documents and technical standards that constitute 'soft' law or guidance governing digital health, including:

- Guiding document issued by the central Chinese government and sectoral regulators: the Guiding Opinions of the State Council on Actively Propelling the Internet Plus Action Plan and ' are some of the policy documents that have been published outlining the central government's advocacy for the development of the digital health sector. The Guiding Opinions of the National Healthcare Security Administration on Actively Promoting Medical Insurance Payment for 'Internet Plus' Medical Services outlines the Chinese government's views on implementing uniform medical insurance payment system for online and offline medical services.
- Technical Review Guidance from the NMPA: various guiding principles issued by the NMPA, such as the Guiding Principles for the Technical Review of Medical Device Software Registration, the Guiding Principles for the Technical Review of Mobile Medical Device Registration, and the Guiding Principles for the Technical Review of the Cybersecurity Registration of Medical Devices, specify the legal requirements for the registration of medical devices.

- Cybersecurity and data privacy: various non-binding national standards are key instruments for implementing China's cybersecurity and data protection and privacy laws. These include, for data privacy, the Information Security Technology: Personal Information Security Specification (2020) (PIS Specification), for network security, various national network security standards, including GB/T 22239-2019 Information security technology — Baseline for classified protection of cybersecurity, GB/T 25070-2019 Information security technology — Technical requirements of security design for classified protection of cybersecurity, GB/T 25058-2019 Information security technology — Implementation guide for classified protection of cybersecurity, and GB/T 28449-2018 Information security technology — Testing and evaluation process guide for classified protection of cybersecurity.

Law stated - 30 November 2021

Liability regimes

What are the key liability regimes applicable to digital health products and services in your jurisdiction? How do these apply to the cross-border provision of digital health products and services?

The improper provision of digital health products and services in China can result in administrative, civil or criminal liabilities. Manufacturers and distributors of a defective digital health product or service may also be subject to tort liability and bear joint and several liability for death, injury, or other damages of consumers caused by the defective product or service. Medical institutions that use defective digital health products or services on patients can also be held liable but have a statutory right of recourse against the responsible marketing authorisation holders or manufacturers of the defective product or service. It is common in China for businesses to purchase liability insurance to cover product liability claims.

Digital health products and services providers bear administrative liabilities and penalties if they violation applicable laws and regulations. For example, liabilities and penalties under Order #739 include revocation of administrative approval, forfeiture of illegal proceeds, confiscation of illegal products, tools, equipment or raw materials, administrative fines of up to 30 times the illegal income, debarment from future regulatory applications for up to 10 years, and suspension of business operations (in serious cases). Responsible individuals may also be subject to personal liability for non-compliance in serious cases. Corporate and personal liability are also possible if the processing of personal information by digital health products or services violates the applicable data privacy laws. For example, a digital health products or services provider that violates the PIPL may be subject to significant penalties for serious violations, including rectification orders, confiscation of illegal gains, business suspension, revocation of business licences, and, most notably, fines of up to 50 million yuan or 5 per cent of turnover in the previous year.

Furthermore, failure to fulfil certain statutory obligations, such as data security and data privacy obligations, may also result in criminal liabilities. For example, illegally selling or providing Chinese citizens' personal information to others may constitute a crime under the PRC Criminal Law and result in fines and up to seven years imprisonment in serious cases.

Many laws and regulations applicable to the digital health sector have an extra-territorial reach, and therefore the liability regimes as explained above are generally applicable to the cross-border provision of digital health products and services.

Law stated - 30 November 2021

DATA PROTECTION AND MANAGEMENT

Definition of `health data'

What constitutes ‘health data’? Is there a definition of ‘anonymised’ health data?

There is no uniform definition of ‘health data’ under Chinese law. Different laws and regulations have different definitions that apply to their jurisdictional scope. However, in general, the following categories of data are generally considered to be ‘health data’ in China: (1) human genetic resources data, regulated under the Biosecurity Law and the Regulations on the Administration of Human Genetic Resources , (2) medical records or medical device data, regulated under the Regulations for Medical Institutions on Medical Records Management , and (3) population health information, regulated under the Population Health Information Management Measures (Trial Implementation) .

Law stated - 30 November 2021

Data protection law

What legal protection is afforded to health data in your jurisdiction? Is the level of protection greater than that afforded to other personal data?

Health data, genetic data, and biometric data are considered sensitive personal information under the PIPL. Sensitive personal information is generally afforded a higher level of protection than ordinary personal information. Processing of sensitive personal information requires the personal information processor to ensure:

- data subjects have given their explicit, separate consent;
- data subjects have been notified of the purposes, necessity, methods, scope, duration of storage, and impact on an individual’s rights and interests of the processing;
- strict protection measures, including encryption, role- and need-based access control mechanisms, are implemented;
- for the processing of personal information of minors under the age of 14, consent of the parent or other guardian of the minor is obtained, and that specialised rules for the processing of such personal information are formulated;
- a privacy impact assessment is performed in advance of such processing;
- before sharing, transferring or publicly disclosing sensitive personal information, data subjects are informed of the types of sensitive personal information involved, the identity of the recipient and their data security capabilities, and provide explicit consent in advance; and
- data subjects are promptly notified of any security breach involving their sensitive personal information.

Law stated - 30 November 2021

Anonymised health data

Is anonymised health data subject to specific regulations or guidelines?

Under the PIPL, ‘anonymised’ data refers to personal information that has been processed so that the identification of specific individuals is impossible and unrecoverable. Anonymised data is no longer considered personal information under Chinese data protection and privacy laws, and is generally regulated the same as ordinary data. It is worth noting, however, that even anonymised data may still be considered as ‘important data’ or ‘medical big data’ and be subject to stricter control over storage and outbound transmission.

Law stated - 30 November 2021

Enforcement

How are the data protection laws in your jurisdiction enforced in relation to health data? Have there been any notable regulatory or private enforcement actions in relation to digital healthcare technologies?

Numerous regulators have overlapping jurisdiction when it comes to enforcing data protection laws in China. Some of the key regulators include CAC, MPS, SAMR, and MIIT.

Since the data protection and privacy laws in China are still relatively new, there have not been very many notable enforcement actions in the digital health sector.

Law stated - 30 November 2021

Cybersecurity

What cybersecurity laws and best practices are relevant for digital health offerings?

The Cybersecurity Law is the primary data security and privacy legislation regulating network operators in China, including digital health products and service providers that operate or manage networks. China has implemented a network security framework known as the 'Multi-Level Protection Scheme' (MLPS) as part of the Cybersecurity Law, under which network operators are required to take appropriate cybersecurity measures corresponding to the classification of their information system (ranging from level 1 to level 5). The latest framework is commonly known as MLPS 2.0. Digital health businesses need to take steps to comply with MLPS 2.0, taking reference of the relevant standards that have been published.

In addition, for digital health businesses, data security incidents involving the theft of personal information is a major risk. Although not mandatory, the PIS Standard is a key guideline for compliance and is widely adopted by Chinese companies. Some of its key principles and requirements that are of particular relevance to digital health businesses include:

- Minimisation principle: the PIS Standard requires businesses to only process types and quantities of personal information necessary for the purposes for which the authorised consent is obtained, and to delete all personal information promptly after the purpose for the processing is achieved.
- Processing of sensitive personal information: the PIS Standard recommends that prior to collecting sensitive personal information (which includes any medical data, genetic data, or biometric information), businesses need to inform data subjects of the necessity of such collection, the consequence of not consenting to the collection and providing such information, and the associated risks in case of data breach. The PIS Standard also requires businesses processing personal sensitive information to conduct a personal information security impact assessment to evaluate the risks that their processing activities could harm the lawful rights and interests of data subjects and how effective their security measures are in mitigating such risks.

Cyber insurance coverage is recommended and is increasing in importance as China's data protection and privacy

regime becomes mature, and the possibility of increased penalties, fines, and liability for cyber breaches increases. Appropriate coverage limits will vary depending on the number of users of the products and services of a digital health business, the type of personal information that is collected and processed, and the size of the digital health business.

Law stated - 30 November 2021

Best practices and practical tips

What best practices and practical tips would you recommend to effectively manage the ownership, use and sharing of users' raw and anonymised data, as well as the output of digital health solutions?

Digital health businesses should bear in mind the minimisation principle discussed above and take a proactive approach to data protection and privacy compliance. Good data protection and privacy practices can only be achieved through a comprehensive, company-wide approach and sustained effort.

In practice, the minimisation principle means that digital health businesses should make conscious decisions concerning what and how much personal information they actually need to collect for their business functions, and whether they actually need to transfer or share personal information to China and non-China affiliates, to third parties, or outside of China.

Lastly, digital health businesses may need to comply with data localisation requirements if they are considered critical information infrastructure operators or when they process personal information beyond a government-prescribed threshold amount. When there is indeed a need to transfer any personal information outside of China, digital health businesses need to meet certain statutory requirements for outbound transfer.

Law stated - 30 November 2021

INTELLECTUAL PROPERTY

Patentability and inventorship

What are the most noteworthy rules and considerations relating to the patentability and inventorship of digital health-related inventions?

Except for certain non-patentable subject matter (for example, rules and methods of intellectual activities, genetic sequences, methods of diagnosing or treating diseases, or animal or plant varieties), in general, inventions that meet the patentability requirements can be claimed in a patent. Both method claims and product claims can be claimed for digital health-related inventions.

Digital health-related inventions (such as software, algorithms, business rules, databases and AI-generated content) that only claim rules and methods for intellectual activities are not patentable. However, such inventions can be patented if they also include technical features (that is, the invention uses technical means to solve technical problems and obtain technical effects).

Law stated - 30 November 2021

Patent prosecution

What is the patent application and registration procedure for digital health technologies in your jurisdiction?

Digital health technologies may be eligible for patent protection in China as a patentable invention (method or device), utility model (device only), or design (device only). Under the PRC Patent Law, the term and examination procedure for these three kinds of patents are as follows:

- invention patent: term is 20 years from the filing date, and procedure requires both preliminary examination and substantive examination;
- utility patent: term is 10 years from the filing date, and procedure requires preliminary examination; and
- design patent: term is 15 years from the filing date, and procedure requires preliminary examination.

The patent application and registration procedure for patentable digital health technologies is generally the same as for other patentable inventions, utility models, and designs. To file a patent application, the owner of the invention or the right to file a patent for the invention needs to engage a PRC patent agent. A patent application, disclosing the invention in a clear and complete manner, must be prepared and submitted to the China National Intellectual Property Administration (CNIPA), and official filings fees must be paid. For an invention patent application, a substantive examination of the patentability of the patent must be conducted by CNIPA.

Law stated - 30 November 2021

Other IP rights

Are any other IP rights relevant in the context of digital health offerings? How are these rights secured?

Data, algorithms, and software are important categories of intellectual property for digital health technologies. In China, software, and to some extent, databases, are protected by copyright. By default, the copyright is owned by the author or company that generates or develops such software or database.

Proprietary know-how that has commercial value are protectable in China as trade secrets. Consequently, trade secrets are another means of protecting digital health technologies that are not suitable for other forms of IP protection.

Law stated - 30 November 2021

Licensing

What practical considerations are relevant when licensing IP rights in digital health technologies?

Some key practical considerations for IP licensing transactions involving digital health technologies include:

- Data rights and ownership: it is important to understand, as between the licensor and licensee, who owns the data generated under the licence agreement, how such data will be used, whether such data will be shared between the parties, who owns the insights or technology derived from the use of such data, and whether revenue resulting from the use of such data or technology will be shared.

- Scope of IP being licensed and rights of access: it is important to clearly define what IP is being licensed, whether it includes all the IP that is needed for a party to exploit the technology, and whether it contains updates or new IP that is later created. For software licences, it is important to clearly define the versions and features of the software being licensed, and whether updates are included.
- Exclusivity v non-exclusivity: it is important to understand which licensed rights are granted on an exclusive basis and which are granted on a non-exclusive basis, as it will impact what a licensee can do with the IP rights obtained and what a licensor can do with the IP rights that are licensed.
- Termination provision: triggers for termination and the effects of termination are usually heavily negotiated provisions in a licence agreement, particularly if licensed rights are granted exclusively.
- Performance targets: the parties often need to determine what are their respective obligations for utilising the licensed IP, and what are the consequences if a party's performance falls short of expectations.
- Regulatory obligations: the parties should ensure to comply with any export control, HGRAC regulations and other data related regulations and may want to set out specific compliance provisions in the agreement.

Law stated - 30 November 2021

Enforcement

What procedures govern the enforcement of IP rights in digital health technologies? Have there been any notable enforcement actions involving digital health technologies in your jurisdiction?

Civil litigation and administrative enforcement actions are the two most relevant options for enforcing IP rights in digital health technologies.

Civil litigations typically occur with the following steps:

- The enforcing party investigates and gathers evidence of infringement.
- The enforcing party files applications for preliminary relief, evidence preservation and property preservation with the People's Court, followed by a formal civil complaint and supporting evidence. The defendant can submit a formal defence and rebuttal evidence. For enforcement of patents, the defendant can file a patent invalidation application with the Patent Re-Examination Board at any time.
- An oral hearing is conducted and decision is rendered by the People's Court.
- Either party can appeal the decision by filing an appeal with the higher-level People's Court.

Administrative enforcement actions typically occur with the following steps:

- The enforcing party investigates and gathers evidence of infringement.
- The enforcing party files an administrative complaint with the CNIPA or its local office or other administrative authority.
- The relevant administrative authority investigates and takes action to obtain evidence of infringement. The defendant can submit a formal defence and rebuttal evidence. Oral hearings may be conducted.

- The administrative authority issues a decision.
- Either party can appeal the decision by filing an administrative lawsuit with the People's Court.

Mindray Biomedical Electronics Co, Ltd v Shenzhen Huasheng Medical Technology Co, Ltd is a recent notable case

involving digital health technologies, which was decided in July 2020. In the case, Mindray sued Huasheng to enforce its patent relating to 'Body Map Operation Methods and Systems for Ultrasound Diagnostic Equipment'. The Supreme People's Court ruled in the Mindray's favour and awarded damages of 1 million yuan to compensate Mindray for its economic losses and reasonable enforcement costs.

Law stated - 30 November 2021

ADVERTISING, MARKETING AND E-COMMERCE

Advertising and marketing

What rules and restrictions govern the advertising and marketing of digital health products and services in your jurisdiction?

The advertising of digital health products is primarily regulated under the Advertising Law (revised in 2021) and the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Dietary Supplements and Food for Special Medical Purposes . The Advertising Law defines advertising activities broadly, covering any channels or media where a distributor of a product or service directly or indirectly markets or introduces the product or service. Where a digital health product is regulated as a medical device, any advertisement of such product requires the prior approval of the local Administration of Market Regulation. In China, common issues with advertisements of medical devices including prohibited off-label advertising, unscientific or misleading statements, guarantees of efficacy or safety, and endorsements by health care professionals, scientific experts, and patients.

The Measures for the Administration of Medical Advertisements regulates the advertising of digital health services. Before publishing a medical advertisement that directly or indirectly introduces medical institutions or medical services, the relevant medical institutions must submit the draft script to and obtain an Examination and Approval Certificate of Medical Advertisements from the local provincial counterpart of the NHC. Medical advertisements can only contain the basic information stated on the medical institution's medical licence, such as the name, address, ownership, type, clinical departments, and number of beds, etc. Medical advertisements cannot contain any reference to medical technologies, diagnostic methods, names of diseases, names of drugs, cure rate guarantees, denouncement of competitors, or the names and images of physicians, patients, or medical education or research organisations. In addition, medical advertisements may not be disguised as news coverage.

Law stated - 30 November 2021

e-Commerce

What rules governing e-commerce are relevant for digital health offerings in your jurisdictions?

The E-Commerce Law sets out specific requirements for use of electronic payments and conclusion of contracts in e-commerce which apply to the offering and selling of digital health products and services online. Buyers and sellers of digital health products and services through e-commerce may agree to adopt electronic payment methods. For digital health products that are considered medical devices, the Measures for the Supervision and Administration of Online Sales of Medical Devices issued by the NMPA also govern their online sale.

Law stated - 30 November 2021

PAYMENT AND REIMBURSEMENT

Coverage

Are digital health products and services covered or reimbursed by the national healthcare system and private insurers?

In China, as a precondition for the reimbursement of the costs of a drug through Basic Medical Insurance (BMI), the drug must be listed in the National Drug Catalogue for Basic Medical Insurance (also known as the Reimbursable Drug List, RDL). Similar to drugs, only treatments or devices included in the Catalogue for Medical Treatment Charges Covered by BMI are reimbursable. The reimbursement landscape for medical devices and medical treatments is more fragmented compared to that for drugs. Specific reimbursement ratios and caps for medical devices and medical treatments are set at the discretion of individual cities and vary significantly across the nation.

Digital health products and services that are listed in the RDL and the Catalogue for Medical Treatment Charges Covered by BMI are reimbursable. For example, artificial intelligence assisted treatment technology is reimbursable in Shanghai and the reimbursement rate is 80 per cent.

An increasing number of private health insurers are expanding their insurance coverage to cover digital health products and services.

Law stated - 30 November 2021

UPDATES AND TRENDS

Recent developments

What have been the most significant recent developments affecting the digital health sector in your jurisdiction, including any notable regulatory actions or legislative changes?

The most significant legislative developments in the past few years affecting the digital health sector in China related to data protection. For the healthcare industry, GB/T 39725-2020 Information security technology – Guide for health data security , a new national standard became effective in July 2021. The guidelines provide recommended methods for classifying and categorising health data, and recommended security measures when processing health data in different scenarios, including clinical research, secondary utilisation, medical devices, connections between commercial insurance and social insurance, and mobile applications.

Law stated - 30 November 2021

Jurisdictions

Australia	Gilbert + Tobin
Brazil	Gusmão & Labrunie
China	Ropes & Gray LLP
Czech Republic	dubanska & co
Germany	Ehlers Ehlers & Partner
India	Chadha & Chadha Intellectual Property Law Firm
Indonesia	ABNR
Ireland	Mason Hayes & Curran LLP
Israel	Naschitz Brandes Amir
Japan	Anderson Mori and Tomotsune
Qatar	Al Marri & El Hage Law Office
Russia	King & Spalding LLP
South Korea	Bae, Kim & Lee LLC
Spain	Baker McKenzie
Switzerland	Lenz & Staehelin
Thailand	Baker McKenzie
United Kingdom	Latham & Watkins LLP
USA	Seyfarth Shaw LLP