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1. Regulatory Framework

1.1 Legislation and Regulation

The primary legislation governing the authorisation, marketing, sale and supply of pharmaceutical products by the US Food and Drug Administration (FDA) is the Federal Food, Drug, and Cosmetic Act (FD&C Act), which has been amended many times over the years to reflect increasing FDA mandates for regulation of pharmaceutical products. The Public Health Service Act (PHS Act) is the specific authority utilised to approve or license biologic (including biosimilar) products. The primary FDA regulations governing drugs and biologics are found at Chapter 21 of the Code of Federal Regulations. Controlled substances, such as opioids, are also scheduled, and subject to quotas and distribution controls, under the Controlled Substances Act administered by the Drug Enforcement Administration (DEA).

A drug is defined as:

- a substance recognised in the US Pharmacopoeia, Homeopathic Pharmacopeia or National Formulary;
- a substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease;
- a substance (other than food) intended to affect the structure or any function of the body;
- a substance intended for use as a component of a drug, but not a device or a component, part or accessory of a device.

A biologic is defined under the PHS Act as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings". Biological products are also included within the drug definition and are generally covered by most of the same laws and regulations, but differences exist in the regulatory approach, particularly with respect to manufacturing processes.

Medical devices are also regulated by the FDA under the FD&C Act, and, although subject to similar intent standards, such products generally are primarily intended to act via mechanical rather than chemical or biological modes of action. Medical devices are classified by risk, and may be exempt from FDA review, subject to a "510(k)" pre-market notification process based upon a showing of substantial equivalence to a "predicate" device, subject to down-classification via the "de novo" submission process, or eligible for full approval via a pre-market approval application (PMA).

The government agencies touching on pricing and reimbursement vary, depending upon the payer programme, and include the Centers for Medicare & Medicaid Services (CMS), the Veterans Health Administration, and state Medicaid agencies. The Department of Health and Human Services Office of Inspector General oversees laws governing fraud and abuse in the sale of biomedical products and healthcare services. The Federal Trade Commission (FTC) regulates the advertising of non-prescription drugs and non-restricted medical devices.

1.2 Challenging Decisions of Regulatory Bodies

Agency decisions may be challenged either informally, via guidance-driven processes governing informal dispute resolution, or via more formal regulatory processes specified under FDA regulations. In addition, a general-purpose vehicle for bringing issues before the agency is the Citizen Petition, which allows the petitioner to bring a request before the agency and initiate a public docket in which comments can be lodged. The FDA also maintains ombudsmen in the various centres reviewing products, whose role is intended to facilitate the resolution of disputes. Although procedures for dispute resolution vary by the specific statutory provisions at issue and the FDA Center responsible for the category of products, such processes generally follow APA standards for permitting due process and creation of an administrative record.

Once administrative processes are exhausted, parties with appropriate standing may challenge FDA agency decisions in court under the Administrative Procedure Act (APA). Although administrative processes vary by category, APA requirements are largely the same across products, and typically involve a demonstration that an agency action was arbitrary or capricious or otherwise not in accordance with governing law.

1.3 Different Categories

Although the default for drug approvals is technically over-the-counter (OTC), ie, non-prescription, status, most initial drug approvals specify that new drug products are subject to prescription drug controls. Prescription drugs must be labelled as such and are subject to physician prescribing and pharmacy dispensing and substitution controls under state law.

However, it is possible to seek an initial FDA approval for the sale of a drug product OTC, or seek to "switch" a prescription product to OTC status by demonstrating that the condition is capable of self-diagnosis and treatment in accordance with labelling. Moreover, over the decades, FDA has also developed OTC monographs that permit the marketing, without approval, of certain OTC drugs that meet the specific terms – ingredients, dosing, directions for use, etc – for that class of drug under the relevant monograph. Such drugs remain subject to establishment registration, listing, labelling and current Good

Manufacturing Practice (cGMP) requirements. Currently pending legislation may liberalise the processes for amending OTC monographs and provide incentives that could reinvigorate OTC product development in the US.

Medical devices may also be restricted to non-restricted (including OTC) or restricted status, depending on their classification and the FDA's determination as to appropriate status under clearance and approval processes.

2. Clinical Trials

2.1 Regulation of Clinical Trials

For drugs and biologics, unless subject to specific exemptions, an investigational new drug application (IND) must be submitted to obtain FDA clearance prior to engaging in clinical research. Such submissions typically include extensive preclinical data, information on chemistry, manufacturing and controls, prior human data and the proposed protocol(s). The FDA has 30 days either to allow the clinical study to proceed or to impose a clinical hold until outstanding issues are resolved. Similar rules apply to medical device research and, depending upon the risk posed by the device, a device study may require the submission of an investigational device exemption (IDE) prior to initiating clinical research. Non-significant risk device studies may be conducted with just Institutional Review Board (IRB)/Ethics Committee approval. The FDA maintains an array of good clinical practice regulations governing clinical research, including study sponsor, IRB, and investigator responsibilities.

2.2 Procedure for Securing Authorisation

As noted, in addition to obtaining approval to proceed with clinical research by filing an IND or IDE, as appropriate, virtually all studies must be reviewed by one or more IRBs prior to initiation. FDA regulations specify the requirements applicable to the composition and activities of IRBs.

2.3 Public Availability of Databases

The US National Institutes of Health maintains a database at www.clinicaltrials.gov, and most controlled, interventional clinical investigations, other than Phase I clinical investigations, of drugs or biologic products subject to FDA regulation, must be registered with the site. The clinicaltrials.gov database has greatly expanded the obligation to include more expansive results information. While there is no general requirement to publish clinical trial data in journals, as a practical matter the industry has pledged to seek such publication where possible.

2.4 Restriction for Using Online Tools

Online tools may be used as long as they comply with applicable requirements (eg, privacy, data security, informed consent and other good clinical practice requirements, and establishing lawful status if such tools incorporate certain regulated medical device functionalities). Particular requirements apply to recruiting subjects for clinical studies, and advertisements for study subjects, whether online or otherwise, must be IRB-approved and limited to basic information.

2.5 Use of Resulting Data

The personal data resulting from clinical trials would be considered protected, although in certain scenarios the sponsor and the FDA will have access to such information, including patient-identifiable information, in order to conduct and analyse the data from the study properly.

As long as any transfer of resulting data to a third party or an affiliate is consistent with contractual obligations, informed consent, and privacy protections, such transfers are permitted.

2.6 Further Requirements for the Creation of a Database

A database containing personal or sensitive data may be subject to both contractual and statutory protections obliging maintenance of data security and privacy. Such data is also typically protected under the Freedom of Information Act, to the extent it has been submitted to a US government agency.

3. Marketing Authorisations

3.1 Assessment Process and Criteria

Such determinations are typically made by assessing the primary mode of action of the product and whether it works, by chemical, biological, mechanical, or other means. If the product has both chemical/biological and mechanical modalities, a Request for Designation may be submitted to FDA to seek a ruling on the proper pathway for approval.

3.2 Granting a Marketing Authorisation

Drug products are approved via New Drug Applications (NDAs), and additional indications, dosage forms, etc, may be added via NDA supplements. Biologic products are approved via a virtually identical process for Biologics License Applications (BLAs). The standard for approval is "substantial evidence" of safety and effectiveness based upon at least one, and typically several, adequate and well-controlled clinical studies, although more flexibility is often shown vis-à-vis drugs used in orphan populations. The typical drug or biologic review process takes ten months after initial acceptance for filing (a 60-day period), although priority review of six months is given to certain drugs and biologics intended to treat serious or life-threatening conditions.

Under the 505(b)(2) NDA process, an applicant may submit an NDA that relies in whole or in part on data and literature that is in the public domain and for which the applicant does not have a right of reference. Generic applicants submitting Abbreviated New Drug Applications (ANDAs) may also rely upon FDA findings with respect to a prior reference listed brand drug, assuming they are not blocked from such reliance by outstanding statutory exclusivities or the terms of listed patents, and they have successfully invalidated or demonstrated non-infringement of the listed patents in court after a certification under the Hatch-Waxman statutory process.

Medical devices may be cleared via a 510(k) pre-market notification or PMA, depending upon the risk classification of the device, and those processes may require from 100 days for a 510(k) submission to a year for a full PMA. Those timelines are subject to goals set by the agency pursuant to user fee legislation. Note that a "de novo" submission may be made to seek down-classification of the device based on its lower risk. FDA will then either determine that the device is Class I or II (permitting submission of a 510(k)), or that the device should remain Class III and subject to a PMA requirement.

Substantial user fees are required to facilitate review of applications, at the high end ranging to approximately USD2.4 million for an NDA or BLA containing clinical data.

3.3 Period of Validity

There is no mandatory re-authorisation or renewal process for approved products. However, the FD&C Act and FDA regulations include processes for the withdrawal or revocation of an approval based upon non-compliance with approval requirements, or a significant safety or effectiveness issue. Such processes can be expedited in the event of an imminent hazard, but processes for challenging a revocation may be invoked in most cases. Such actions are rare, and in most cases a manufacturer will withdraw a product voluntarily rather than pursue a formal hearing. In general, a marketing authorisation may not be revoked merely because the product has not been placed on the market, although a failure to market an orphan drug could result in a loss of orphan exclusivity.

3.4 Procedure for Obtaining a Marketing Authorisation

As noted, the pathways for approval of drugs consist of the submission of an NDA (including a 505(b)(2) NDA relying on data for which the applicant does not have a right of reference), and the ANDA for generic products, which demonstrates equivalence to a reference listed drug. A biologic is licensed via the submission of a BLA, although that process is largely the equivalent of an NDA submission. A biosimilar application demonstrates that the biosimilar is, based on the totality of the evidence, either "highly similar" to, or interchangeable with, a reference biologic. To date, no such submission has resulted in a determination of interchangeability.

The FDA is authorised to require paediatric studies of drugs or biologics when other approaches are insufficient to ensure that the products are safe and effective for use in children. The Agency may also issue a written request for paediatric research, and if the sponsor fulfils the data request, it may obtain six months of paediatric exclusivity.

As noted, changes to an existing marketing authorisation may be obtained through supplements or amendments to existing applications. With respect to medical devices, the submission of an additional 510(k) submissions can result in the clearance of significant changes to previously cleared device products, and a PMA may also be supplemented or amended.

In many cases, the transfer of a clearance or approval without manufacturing site or product changes requires only fairly simple notifications to the FDA to transfer the authorisation or application and appropriate amendment of product listings. Changes in manufacturing or other risk factors may trigger approval requirements.

3.5 Access to Unauthorised Products

The FDA maintains regulations permitting expanded access to investigational products. Such expanded access INDs and IDEs may relate to an individual patient (often called a "compassionate use"), or may allow broad use by patients not eligible for controlled clinical trials, depending upon the known risk-benefit and availability of alternative treatments. Sponsors of such INDs may not charge patients for the investigational drug without specific authorisation from the FDA permitting cost recovery.

In addition, the 2018 "Right to Try" Act permits certain eligible patients to have broad access to eligible investigational drugs in certain circumstances. To date, most companies have shown a reluctance to permit their products to be used via this pathway in lieu of the more traditional IND pathway.

There is also a Humanitarian Device Exemption (HDE) pathway for approval of a Humanitarian Use Device (HUD) intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the USA per year. An HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.

3.6 Ongoing Obligations

Every drug, biologic or device product is subject to ongoing requirements relating to establishment registration, product

listing, compliance with cGMPs/quality systems, track and trace requirements, and safety/adverse event reporting regulations. In certain cases, the FDA may require closer, ongoing oversight of a drug or biologic under a Risk Evaluation and Mitigation Strategy (REMS), or mandate post-market studies or trials. The FDA also has extensive authority to require post-market studies or trials as a condition of drug, biologic, or PMA medical device marketing authorisations, subject to specific standards.

3.7 Third-Party Access to Pending Applications

While the FDA does release approval letters and – after review for redaction of confidential and trade-secret information – summary review and approval documents, the FDA does not currently publish "Complete Response Letters" that reject an application under review. Available information on approved products may be obtained via the FDA's Drugs@FDA website. Often, extensive information about pending applications is released in the form of briefing papers and presentations used at FDA Advisory Committee meetings. The FDA does not reveal the existence of pending INDs or IDEs unless the sponsor has publicly acknowledged the filings.

Third parties may submit requests for information under the Freedom of Information Act (FOIA), although there are a variety of exceptions from disclosure, and there is a major FDA backlog of requests. Most importantly, the FDA has an obligation under the FOIA to refrain from publication of trade secret or confidential commercial or financial information. Sponsors/applicants are afforded an opportunity to review potential releases of information and request confidential treatment under those FOIA exceptions.

3.8 Rules Against Illegal Medicines and/or Medical Devices

In 2013, Congress enacted the Drug Supply Chain Security Act (DSCSA), which mandates steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the USA. The objective is to enhance the FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful, and improve detection and removal of potentially dangerous drugs from the drug supply chain.

Although for medical devices a Unique Device Identification System is being implemented, that identification system serves various purposes, including providing a standardised identifier that will allow manufacturers, distributors and healthcare facilities to manage medical device recalls more effectively and providing a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion.

FDA's Office of Criminal Investigation (OCI) has primary responsibility for policing drug and medical device counterfeiting and diversion, and at times companies will approach OCI and other law enforcement bodies to seek an investigation and enforcement action.

3.9 Border Measures

The FDA and Customs and Border Protection work together to identify and detain counterfeit medical products, and it is possible to work with those agencies to seek enhanced surveillance with respect to potential importation of such products. The FDA has extensive powers to stop products at the border if they are suspected of being adulterated or misbranded. In addition, companies may file actions seeking an investigation under Section 337 of the Tariff Act with respect to unfair acts in the importation of articles, although such actions may fail if positioned as an attempt to enforce the FD&C Act privately.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Manufacturing Plants

In general, manufacturing plants are not subject to a separate authorisation from the related product approvals, although they must be registered with the FDA (and the products produced at the facility must be listed as associated with the establishment). Moreover, in most cases the FDA will conduct a pre-approval inspection of the facility before approving a drug or device, and such establishments are also subject to both routine (typically every two years) and for cause (eg, in response to a product defect and recall) inspections.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

In general, wholesale activities are subject to licensure requirements at the state level and registration as distributors at the federal level. The requirements and length of such licences vary by state.

The FDA may inspect any facility holding drugs for shipments, and state inspection activities and fees vary greatly. Significant additional requirements administered by the Drug Enforcement Administration and states apply to wholesale trade in controlled substances.

The authorisation to trade in pharmaceuticals varies greatly by state, but most pharmaceutical distributors must hold a state

licence. Such requirements often do not apply to entities that are not physically handling drug products.

5.2 Different Classifications

Drugs may be either prescription (as defined under state law, generally subject to prescription by a designated healthcare practitioner and dispensing by a licensed pharmacist), or over-the-counter (permitting sale without intervention by a healthcare practitioner or pharmacist). Certain products (pseudoephedrine) are required to be kept behind the pharmacy counter due to specific statutory requirements, and the FDA is exploring methods for expanding direct availability of products with pharmacist-only involvement, such as via use of mobile apps and kiosks in pharmacies permitting education and diagnostic screening.

6. Import and Export of Pharmaceuticals and Medical Devices

6.1 Governing Law and Enforcement Bodies

The FD&C Act and general import and export administration laws govern the import/export of pharmaceuticals and medical devices. In general, imported medicines and medical devices must be subject to an approval or clearance, if applicable, in the USA. Only the original manufacturer of a drug may reimport a drug product back into the United States. The importation of even an identical drug produced at a facility that is not inspected in the course of the US approval would be considered unlawful. Limited exceptions are permitted for individuals to engage in personal, physical importation of foreign products for their use based upon a prescription from a healthcare professional and a lack of alternatives in the USA.

At the border, the primary regulators are the FDA, administering the FD&C Act for potential violations, and US Customers and Border Protection, administering the broad array of US laws governing customs matters. Other agencies, such as the Department of Commerce and Department of Agriculture, may have responsibilities as well, depending on the nature of the imported article.

6.2 Importer of Record

Importers of record may be designated by the manufacturer or distributor, and they have specific responsibilities. A US importer of record (ie, the owner, purchaser, or licensed customs broker designated by the owner, purchaser, or consignee) files entry documents for the goods with the port director at the goods' port of entry. It is the importer of record's responsibility to arrange for examination and release of the goods. Initial importers may also be responsible for registration and listing requirements as well. Customs requires the importer of record to file an importation bond, typically, at least equal to three times the invoice value of the goods.

6.3 Prior Authorisations

A drug or medical device must be cleared or approved (and the product properly listed in association with a registered establishment), or the subject of an active IND or IDE, in order to be lawfully imported. Exceptions are made for importation of a very limited amount of a product for personal use, and the FDA will work with potential importers in certain situations (eg, compassionate use, short supply) to expedite satisfaction of regulatory requirements.

6.4 Non-tariff Regulations and Restrictions

Upon entry into the USA, declarations and information must utilise the Customs Harmonized Tariff Schedule codes according to the Harmonized Tariff Schedule of the US (HTSUS), and FDA product codes. Such declarations are subject to specific regulations issued by Customs and the FDA. A failure to classify a product properly may result in an improper payment of Customs duties, and associated penalties.

6.5 Provisions on Trade/Regulatory Facilitation

The USA is a member of the World Trade Organization and has free trade agreements in effect with 20 countries. Some are re bilateral agreements, but others are multilateral in nature. The USA is also a party to Trade and Investment Framework Agreements that provide frameworks for governments to discuss and resolve trade and investment issues at an early stage, as well as bilateral Investment Treaties to help protect private investment, develop market-oriented policies in partner countries, and promote US exports. The US FDA is also a party to various memoranda of understanding and mutual recognition agreements to facilitate global discussions and risk assessments with respect to, for example, global inspections.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control

The USA has little in the way of price controls for pharmaceutical products and medical devices. Therefore, in most cases, the manufacturer of a product sets the initial price and adjusts prices (including rebates and other price concessions) over time in response to market conditions. However, there are a few federal laws that cap pharmaceutical prices to certain purchasers or require minimum rebate levels:

- manufacturers must sell their outpatient drugs to "covered entities" (generally certain clinics and hospitals thought to

serve safety net functions) at or below a statutorily set ceiling price under the section 340B drug-discount programme;
- manufacturers must sell brand name drugs to four federal agencies (the Department of Veterans Affairs, the Department of Defense, the Public Health Service and the Coast Guard) at or below a "federal ceiling price" determined by a statutory formula; and
- manufacturers must pay a rebate set by a statutory formula on each unit of their outpatient drugs paid for by the Medicaid programme. This is not literally a "price-control" programme because it only controls the rebate paid to Medicaid after the drug has been dispensed or administered – the price that Medicaid pays up front to the dispensing pharmacy or to a physician office or clinic that administers a drug is not affected by the Medicaid rebate programme.

7.2 Price Comparison

The price level of a pharmaceutical or medical device does not depend on the prices for the same product in other countries. However, the current Administration is currently considering the issuance of a proposal for an international pricing index model that would introduce the notion of reference pricing to the US. The exact contours of this proposal are not currently known.

7.3 Reimbursement from Public Funds

The largest healthcare programme in the United States today is the Medicare programme, which provides healthcare coverage for people who are 65 and older, disabled (for two years or more), or have end-stage renal disease. Medicare accounts for roughly 20% of US health spending. Most pharmaceutical products are eligible for some form of Medicare coverage, either through:

- Part B (Medicare's traditional outpatient benefit, which covers a small but important set of drugs, such as physician-administered drugs);
- Part D (the new Medicare drug benefit that started in 2006, which provides broad coverage for pharmacy-dispensed oral drugs); or
- Part A (Medicare's inpatient benefit, which covers drugs furnished as part of covered inpatient hospital stays and in certain other inpatient settings).

The second-largest healthcare programme today – accounting for roughly 17% of US health spending – is the Medicaid programme, which is a joint federal-state programme providing coverage for certain low-income individuals (with the specific eligibility criteria varying by state). Medicaid is run chiefly by states, with federal government oversight, and state Medicaid programmes generally provide broad coverage for prescription drugs. Medicaid programmes have sometimes imposed coverage restrictions on high-cost drugs that arguably conflict with their statutory obligations.

7.4 Cost Benefit Analysis

The process and evidence that US payors use to make decisions about pharmaceutical and medical device coverage varies widely by payor (and is not always entirely transparent). These variations can include the criteria considered appropriate for evaluation (eg, whether a product's cost or cost-effectiveness is taken into account in coverage decisions), the scientific rigour of the evidence considered and the weight placed on the types of evidence considered, the decision-making body and the processes for making coverage decisions, and the legal standards that apply to the coverage decision-making process and the resulting package of covered products and services. There are several organisations engaged in developing value-assessment tools of various sorts, which essentially are tools designed to help payors, healthcare providers and patients compare certain demonstrated outcomes of competing pharmaceuticals on a systematic basis and thus to reach conclusions about their value in a more systematic and rigorous way than is common today.

7.5 Prescriptions and Dispensing

Pharmacists are paid for dispensing prescriptions by the patient's insurer (assuming the patient is insured and the product is covered) and the patient. The circumstances in which pharmacists may dispense a substitute for the prescribed product without obtaining the prescriber's authorisation are governed by state law. State laws on this issue can vary, but generally they permit pharmacists to substitute a product approved by the FDA as a generic equivalent for the prescribed product (unless the prescription specifically states "dispense as written" or a similar phrase indicating no substitution).

Over the past several years, the standards for permitting pharmacists to substitute a "bio-similar" product for a prescribed biological have been a topic of considerable debate. The provisions of these laws vary, but often they permit bio-similar pharmacy-level substitution only if the substituted product has been designated as "interchangeable" with the prescribed biological by the FDA, which has not occurred to date, the prescriber and the patient are both notified of the substitution, and the pharmacist maintains records of the substitution. At present, only a small number of bio-similar products have been approved in the USA, and none has been deemed interchangeable with the reference biologic.

8. Digital Healthcare

8.1 Rules for Medical Apps

The FDA has been very active in providing guidance in this area, and has carved out large categories of apps and platforms from regulation. The US Food and Drug Administration (FDA) has issued several guidance documents designed to "encourage innovation" and "bring efficiency and modernisation" to the agency's regulation of digital health products. The guidance documents address, in part, the important changes made by Section 3060 of the 21st Century Cures Act (Cures Act) to the medical device provisions of the FD&C Act that expressly excluded from the definition of medical device five distinct categories of software or health products. The FDA's extensive guidance documents in this area include guidance on Clinical and Patient Decision Support software, regulation of software as a medical device (SaMD), and general wellness products, which establishes common principles for regulators to use in evaluating the safety, effectiveness, and performance of SaMD. The FDA has also issued a Discussion Paper on the regulation of SaMD incorporating artificial intelligence.

8.2 Rules for Telemedicine

The FDA does not regulate the practice of medicine, and the Agency generally defers to the states to determine what is a valid physician-patient relationship and prescription. Although telemedicine is growing in the US, and more and more physician consultations are being provided online via chat-based or video examinations, the permissibility of such activities vary by state. Various laws govern issues such as the corporate practice of medicine, minimum rules for a genuine patient relationship, cross-border prescribing and lab orders, privacy, and payments and referrals to telemedicine physicians. The availability of electronic prescribing also varies by state, although states generally permit online dispensing of approved drug and medical device products pursuant to valid prescriptions.

8.3 Promoting and/or Advertising on an Online Platform

Medicinal and medical device products may generally be promoted online, on company websites, and via social media. However, such media present special challenges to ensure that the promotion is fairly balanced, truthful and non-misleading, transparent as to the company's involvement, and adequately provides safety information in particular. The FDA has developed several guidance documents in this area to provide information to a company regarding when the Agency considers user-generated information on a company's webpage or social media to be promotional (largely based on the level of control over the site and placement of information) and how to convey information properly in a character-limited social media environment. Additional rules apply to online marketing practices, such as the FDA and FTC requirements pertaining to endorsements and testimonials in online promotion.

8.4 Electronic Prescriptions

Electronic prescribing of drug products is governed by state laws and Board of Pharmacy rules. Most states do permit some form of electronic prescribing, although the specific rules (such as for specifying use of the brand name drug, etc) vary by state. Special rules may apply to interstate prescribing, particularly with respect to controlled substances, and licensure in multiple states may be required where reciprocity in licensure recognition is not provided.

8.5 Online Sales

Online sales of prescription drug and device products are permitted if there is otherwise a valid prescription for the product and the pharmacy is duly licensed in the states to which the products are shipped. Special rules apply to certain controlled substances. To the extent prescribing of the drug or device also occurs online, the prescriber must satisfy state requirements pertaining to valid physician-patient relationships and telemedicine-based prescribing. Online sales of drugs into the United States from ex-US pharmacies, whether or not pursuant to a valid prescription, are generally prohibited.

8.6 Electronic Health Records

In addition to FDA rules, addressed previously, regarding digital tools that convey health records and images, there are many other aspects to the regulation of electronic health records in the US. In particular, the HHS Office of the Coordinator for Health Information Technology (ONC) is responsible for implementing statutory provisions relating to advancing inter-operability, clarifying HIPAA privacy rules, prohibiting information blocking, and enhancing the usability, accessibility, and privacy and security of health IT. The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 provided HHS with the authority to establish programmes to improve healthcare quality, safety, and efficiency through the promotion of health IT, including electronic health records and private and secure electronic health information exchange.

9. Licensing

9.1 Customary Deal Structures

Variants of all of the deal structures listed above and combinations of such deal structures (eg, an option with a different trigger or a designated time period in which it must be exercised) may be used. The scope and timing of the licence, whether it is exclusive or not, and whether the licence may be further sublicensed or transferred are critical points of negotiation. Life sciences commercial arrangements may also include development

agreements and manufacturing agreements. Often, research collaboration, option and licence arrangements incorporate milestone payments for a party's completion of regulatory events and/or commercial success. Sometimes, there may also be a royalty and/or profit-share component, especially if a party has an existing product that may compete with the product regarding which the parties are collaborating.

9.2 Dispute Resolution Provisions

Depending on the complexity of the deal, typically, disputes are often first referred to the relevant joint sub-committee, eg, a Joint Manufacturing Committee. If that committee is unable to resolve the issue, the issue is often further escalated to the Joint Steering Committee or to a designated party or executive with the ability to resolve that type of issue definitively. In the event of continued disagreement, the senior executives of each party typically try to meet to resolve their differences amicably. If the dispute is not resolved with a certain time period (often 30 days), the matter is typically referred to confidential, final and binding arbitration. Agreements sometimes specify certain measures to streamline the proceedings, such as efficient and cost-effective discovery, limitation of the time available for testimony, limitations on the duration of the hearing, and a requirement for the arbitrator(s) to render their written final, binding, non-appealable decision and award (including essential findings and conclusions on which the decision and award are based, as well as the calculation of damages awarded) within 30 days of the close of the proceedings. Typically, each party also often has the right to seek preliminary and permanent injunctive and other equitable relief from a designated court to prevent or curtail any actual or threatened breach of the IP and confidentiality provisions that is reasonably likely to cause that party irreparable harm.

9.3 Diligence Obligations Provisions

Parties often heavily negotiate the level of effort each party must use when developing and commercialising the products in question. There is established case law regarding how "commercially reasonable efforts" and "best efforts" have been interpreted in the relevant jurisdiction, but parties may also use custom variants such as "commercially reasonable best efforts." Since the level of efforts exerted in connection with the agreement is one of the most likely points of disagreement between the parties, it appears that there is a trend among parties towards defining these terms with reference to an objective standard. For example, a definition could include reference to the efforts that a company with similar products at a similar stage of development or commercialisation would reasonably be expected to employ. Often, licensors also seek to have licensees commit to very specific diligence requirements, either in place of or to clarify general diligence obligations. Typically, licensees with market power or who are paying significant licensing fees resist being held to specific obligations and instead argue that they are sufficiently financially incentivised to expend significant efforts to develop and commercialise the relevant product and their decision-making ability to maximise the returns associated with the product should not be hampered by the requirement to perform certain specific tasks that were determined years prior to the actual commercialisation of the product.

9.4 Change of Control

The treatment of a change-in-control event depends on the stage of relevant assets, the magnitude of the deal, and the nature of the parties. For example, the change of control provision may look different in a deal between two large multinational pharma companies as opposed to between a pharma company and a small biotech or between two small biotech companies. Generally, assignment of the agreement in its entirety consistent with the assignment/change-of-control clause is permitted without the other party's prior written consent. At times, a licensee may have the ability to terminate the agreement in the event of a change of control of licensor. The greater the complexity and economics of the deal, the greater the likelihood of inclusion of a robust clause clarifying that a change of control does not result in the licensing of any intellectual property or technology of the merger partner or acquiror. If the agreement includes a non-compete, the parties often also incorporate a process to be followed in the event a party is acquired by a third party that possesses rights in a competing product. Often, life sciences licensing deals include a statement that any assignment or attempted assignment by either party in violation of the terms of the assignment/change-of-control section is null, void and of no legal effect.

9.5 Termination

The consequences of termination vary based on the reason for termination as well as the nature and stage of the licensing transaction. Often, licence agreements expressly account for different termination scenarios in the event of a party's bankruptcy, change of control of a party, breach by licensor or licensee, and by the licensee for convenience. For example, in the event of termination due to the licensor's bankruptcy, the agreement may include clauses more protective of the licensee than in the event of termination by the licensor due to breach by the licensee. If a licensee has made a significant up-front payment, it may retain greater licence rights in the event of termination, or it may seek to be repaid certain amounts in the event of early termination. The effects of termination may vary by territory, eg, the co-commercialisation territory versus in the licensee's territory. Certain payments and royalties may be adjusted in the event of early termination, particularly in co-commercialisation deals. Whether any licences continue depends on the facts and circumstances of the particular transaction.

10. Patents

10.1 Applicable Laws

The statutory framework for US patent law is generally set out in United States Code Title 35. The Leahy-Smith America Invents Act (AIA) effected sweeping changes to US patent law; one of the most significant of these changes was to bring the USA largely into compliance with the rest of the world with respect to prior art determinations. Pre-AIA, the USA was considered a "first inventor" jurisdiction (ie, the first person to invent the invention was entitled to the patent); post-AIA, the USA is a "first-inventor-to-file" jurisdiction approaching the "first-to-file" methodology employed virtually everywhere else in the world. Specific statutory provisions indicate whether they apply pre-AIA, during a transitional period, or during a certain date range.

As explained in further detail below, in the USA patent protection and certain regulatory exclusivities may share certain traits but are distinct. The Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, amended the FD&C Act and affected the government's regulation of generic drugs. Hatch-Waxman provides for both brand product exclusivities as well as 180-day exclusivity to companies that are the "first-to-file" an ANDA against branded drug patent-holders. This regulatory exclusivity is in addition to the patent term of patents claiming the branded drug and a statutory, 30-month stay of approval permitted in the event of patient litigation.

Although not technically a patent law, the Biologics Price Competition and Innovation Act of 2009 amended the Public Health Service Act to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product.

In the wake of two 2012 US Supreme Court decisions regarding what constitutes patentable subject matter, companies have sought to distinguish their inventions from laws of nature and unpatentable phenomena through narrower claims drafting. In 2018, the Federal Circuit in Vanda Pharmaceuticals Inc v West-Ward Pharmaceuticals further clarified that method of treatment claims involving treatment steps are not directed to a judicial exception under the Supreme Court's patent eligibility analysis. This is in stark contrast to diagnostic claims, such as the claims at issue in the 2019 case of Athena Diagnostics, Inc v Mayo Collaborative Services, which the Federal Circuit has consistently held invalid as patent-ineligible. The Supreme Court denied certiorari in both the Vanda and Athena cases in early 2020. The US Patent and Trademark Office (USPTO) regularly updates and publishes a Subject Matter Eligibility Guidance to improve the clarity, consistency, and predictability of examination outcomes regarding patentable subject matter. Nonetheless, in Cleveland Clinic Foundation v True Health Diagnostics, the Federal Circuit stated that it is not bound by USPTO's guidance. In June 2019, the Senate Judiciary Committee's Subcommittee on Intellectual Property held three hearings on the topic of patent eligibility law reform in an effort to provide clarity and predictability in this area of law to support innovations in the pharmaceutical industry while balancing concerns from the high tech industry. The proposed reform currently remains a draft bill.

To be patentable under US law, an invention must be: (i) patentable subject matter; (ii) novel; and (iii) not obvious. Patentable subject matter includes "any new and useful process, machine, manufacture, or composition of matter" (35 U.S.C. §101). Novelty requires that the invention has not previously been "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention" (35 U.S.C. §102). Finally, an invention must not be obvious – ie, it cannot be the case that "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains" (35 U.S.C. §103).

In addition to these requirements, a patent must "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention" (35 U.S.C. §112).

There are no requirements specific to pharmaceutical products or medical devices, but various claim-drafting structures and statutory requirements are commonly at issue in cases involving pharmaceuticals or medical devices.

10.2 Second and Subsequent Medical Uses

Patent protection is available for new uses of known compounds, processes, manufactures, etc, that satisfy the general requirements for patentability (including novelty and non-obviousness). Claims may be directed to "methods of treatment".

A new dosage regime may be patentable if it satisfies the requirements for patentability. Such claims are often subject to obviousness challenges.

A claim could be directed to a method of treating a patient suffering from new disease X by administering an effective amount

of known compound Y to the patient. A claim could also be directed to a method of treating a selected patient having disease X by administering compound Y at dose Z to the patient, wherein the selected patient is tested positive for a biomarker.

Direct or indirect infringers as well as inducers of infringement may be sued, although as noted above, induced infringement can be found only when one "party" performs every step of a patent.

10.3 Patent Term Extension

35 U.S. Code §§ 154 and 156 address certain adjustments and extensions of patent term, with Section 156 being particularly applicable to drugs and biologics. Certain medical devices may also be eligible for patent-term extension; however, such devices must be reviewed and approved via a PMA. The FDA assists the USPTO in determining a product's eligibility for patent-term restoration and provides information to the USPTO regarding a product's regulatory review period. The USPTO is responsible for determining the period of extension subject to statutory requirements.

As noted above, the FDA may grant certain exclusive marketing rights upon approval of a drug that may or may not run concurrently with a patent. Exclusivity may be granted from five years for a new chemical entity, three years for a new indication requiring submission of eligible data, up to seven years of market exclusivity for orphan drugs, and 12 years for innovator biologics.

A third party may file a due diligence petition challenging the FDA's regulatory review period determination by alleging that an applicant for patent-term restoration did not act with due diligence in seeking FDA approval of the product during the regulatory review period. As far as is known, to date, no due diligence petitions have been submitted to the FDA.

10.4 Patent Infringement

Infringement may occur if the defendant has made, used, sold, offered to sell or imported an infringing invention or its equivalent. A generic applicant may file an ANDA, which allows that applicant to rely on the safety and efficacy studies supplied by the brand name manufacturer if the generic manufacturer shows that its generic product contains the same active ingredient as, and is bio-equivalent to, the brand-name drug listed in the Approved Drug Products with Therapeutic Equivalence Evaluations publication, commonly known as the "Orange Book". In doing so, the generic applicant must make one of four certifications with respect to any patents associated with the drug. The fourth is that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" (21 U.S.C. §355(j)(2)(A)(vii)). Such a "paragraph IV" certification is deemed a constructive act of infringement, and the patent-holder then has 45 days to file an infringement lawsuit against the ANDA applicant. If such a lawsuit is filed, the FDA generally may not grant final approval of the ANDA for 30 months after the filing date or until the ANDA filer prevails in litigation. If patent validity and infringement remain unresolved after the 30-month stay, the FDA may approve the ANDA.

The Biologics Price Competition and Innovation Act (BPCIA) provides a conceptually similar (though procedurally different) framework by which the filing of an abbreviated Biologics Licence Application (aBLA) by a bio-similar applicant is an artificial act of infringement giving rise to a statutorily prescribed process governing subsequent patent infringement litigation and bio-similar regulatory approval. There is no equivalent statute and regime for medical devices.

For patent infringement, the threat of infringement can form the basis of a declaratory judgment action, which can examine the validity of patents and whether the action constitutes infringement. Because this action is brought by the alleged infringer, the alleged infringer can select the venue for the case, which can have great strategic value in US patent litigation. However, because many patent-owners desire to avoid a declaratory judgment action, notice letters and cease-and-desist letters are not as commonly used as in the past, and patent litigation suits are often filed before the alleged infringer could claim that the threat of infringement exists.

10.5 Defences to Patent Infringement

Under 35 U.S.C. § 271(e)(1), it is not an act of infringement to make, use, offer to sell or sell within the USA or import into the USA a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products". In Merck KGaA v Integra Lifesciences I, Ltd, the US Supreme Court held that the statute exempts from infringement all uses of compounds that are reasonably related to submission of information to the government under any law regulating the manufacture, use or distribution of drugs.

Compulsory licences are available only in very specific situations, and generally not under patent law. For example, the US National Institutes of Health may, under certain circumstances, threaten to issue a compulsory licence if a licensee has failed to take effective steps to pursue the government-licensed invention or in certain scenarios involving public health need, but has never done so.

10.6 Bringing Proceedings

Typically, the patent-owner brings the suit alleging patent infringement. Depending on the wording of the licence agreement, an exclusive licensee may also have standing to enforce the licensed patent.

Remedies may include a temporary or permanent injunction, destruction of infringing articles, the award of damages (including the infringer's profits) and, in certain limited circumstances, attorneys' fees.

Patent litigation is much like other civil litigation in the federal district courts in the USA (including a very high settlement rate). First, the plaintiff files a complaint alleging infringement of one or more US patents. Then, the plaintiff serves the complaint on the defendant, who typically answers by alleging non-infringement and asserting defences such as patent invalidity and other equitable defences. In Limelight Networks Inc v Akamai Technologies Inc et al, the Supreme Court held that induced infringement can be found only when one party performs every step of a patent. The Federal Circuit also issued a few decisions addressing claims of invalidity based on the theory that a combination of prior art would be obvious to try and issues of double patenting and patent-term extension. The defendant may also assert a counterclaim, such as a declaratory judgment of non-infringement. A case-management conference regarding scheduling, among other matters, is required. Certain district courts may also have local patent rules that set forth additional requirements. Next, fact and expert discovery are conducted, which typically includes depositions, document requests, interrogatories, expert reports and the like. Often, a claim construction hearing (also known as a Markman hearing) occurs, in which the parties ask the court to interpret certain terms of claims in the patent(s) at issue. The parties also typically file various motions, such as a summary judgment motion of patent invalidity.

If the case proceeds, pre-trial briefing and then trial (by judge or jury) and post-trial practice occur. A jury may render an opinion as to whether the patent is invalid. An appeal may be taken to the Federal Circuit and then to the Supreme Court if the Supreme Court grants a petition for certiorari.

In addition to raising invalidity as a defence in court, a potential infringer (or any third party) can challenge the validity of a patent in proceedings before the Patent Trial and Appeal Board (PTAB). A "post-grant review" permits a person who is not the owner of a patent to challenge a patent's validity on any ground that could be raised under §282(b)(2) or (3) no later than nine months after the date of the grant of the patent (35 U.S.C. §321). An "inter partes review" (IPR) may be requested by a person who is not the owner of a patent after the later of nine months after the grant of the patent or the termination of a post-grant review, if one has been instituted (35 U.S.C. §311(a), (c)), but may not be filed more than one year after the complainant has been served with a complaint alleging infringement. The validity of a patent subject to an IPR can only be challenged on a ground that could be raised under §§102 or 103, and only on the basis of prior art consisting of patents or printed publications (35 U.S.C. §311(b)). In SAS Institute Inc v Iancu, the Supreme Court did away with the PTAB's prior practice of "partial institutions" of IPR challenges – going forward, the PTAB must decide the validity of all challenged claims when it institutes an America Invents Act review of a patent. In Arthrex v Smith & Nephew, Inc, a three-judge panel at the Federal Circuit ruled that the statutory scheme for appointing PTAB Administrative Patent Judges (APJs) violated the Appointments Clause of the US Constitution. Under Anthrex, patent-owners may bring Appointment Clause challenges to seek remand and rehearing of unfavourable IPR decisions.

10.7 Available Procedures

As previously described, an ANDA filer must make one of four certifications with respect to any patents associated with the drug. It is possible that, after making a Paragraph IV certification, the patent-holder may elect not to file an infringement lawsuit. If the patent-holder does not bring suit, the FDA may approve the ANDA. An ANDA filer may not file a declaratory judgment suit during the 45-day period in which the patent-holder may elect to bring a suit. If the patent-holder files suit against the generic applicant within the 45-day period, the generic may file a declaratory judgment counterclaim, as long as an actual case or controversy continues to exist. A generic drug-maker may be able to request correction or delisting of a patent claim from the Orange Book as part of a counterclaim or non-infringement declaratory judgment action.

An ANDA filer and the patent-holder may also reach a licensing or other agreement, although such "reverse payment" settlements can be subject to antitrust scrutiny.

The phrase "clearing the way" is not a term of art in US patent law, but a generic drug manufacturer may launch "at risk" if patent validity and infringement remain unresolved after the 30-month stay and FDA approves its ANDA. In such cases, the generic may be liable for damages if the patent(s)-in-suit are ultimately held to be valid and infringed.

An NDA includes patent information for listing in the FDA "Orange Book" and the FDA considers patent listing as part of the approval process for brand drug applications. If a patent that covers the drug exists, marketing approval will not be granted to a generic until the patent has expired or is found to be invalid.

11. IP Other Than Patents

11.1 Counterfeit Pharmaceuticals and Medical Devices

Trade mark and trade dress owners can sue manufacturers and sellers of counterfeit pharmaceuticals and medical devices for infringement. Additionally, a general exclusion order can be sought in the International Trade Commission (ITC), which can help to combat counterfeits that are being imported into the USA. Under the general exclusion order, any such infringing articles would be seized at the border by customs.

The possession, trafficking, and purchasing of counterfeit pharmaceuticals and medical devices can also be criminally actionable on the federal or state level.

11.2 Restrictions on Trade Marks

A "US adopted name" (USAN), which is a non-proprietary name reviewed by the World Health Organization, is necessary to market a pharmaceutical in the USA. The USPTO reviews and registers federal trade marks (pursuant to the Lanham Act). In doing so, the USPTO considers the likelihood of confusion with other marks and whether the mark is distinctive, along with whether the mark is a surname, likeness, geographically descriptive of the origin of the goods, disparaging or offensive, a foreign term that translates to a descriptive or generic term or is purely ornamental. The US Trademark Trial and Appeal Board (TTAB) hears petitions related to the status of trade marks (including their cancellation). The TTAB may cancel a mark if it finds that a registrant was using the mark to misrepresent the source of the corresponding goods, or differences with prior marks do not offset the likelihood of confusion.

The FDA has authority under the FD&C Act to determine whether a pharmaceutical is "misbranded" – ie, "its labelling is false or misleading in any particular" (21 U.S.C. § 352(a)), which can be due to the proprietary name of the product, which the FDA must approve as part of the drug application.

The Lanham Act and the Tariff Act may provide a basis to bring claims in a federal district court against parallel importers for damages and injunctive relief. Any injunction would be enforced through the federal courts rather than Customs and Border Patrol. Sometimes, the district court action is stayed pending the outcome of an International Trade Commission (ITC) proceeding.

Parallel importation may violate Section 337 of the Tariff Act, which grants the ITC jurisdiction to investigate claims of trademark infringement. The ITC cannot award damages, but can issue exclusion orders that are enforced by Customs and Border Patrol. The ITC can bar the importation of items that infringe US trade marks, copyrights or patents.

Customs and Border Patrol works with the FDA to prevent parallel import. Trade mark-owners typically contact the FDA and then the FDA contacts Customs and Border Patrol.

11.3 IP Protection for Trade Dress or Design

Trade dress protection is available for colour, shape (including pill shape) and packaging that identifies the source of the product and otherwise distinguishes the product, but is not purely functional or likely to be confused with the trade dress of another product.

11.4 Data Exclusivity

For pharmaceuticals, under the Hatch-Waxman Act described previously, there is a period of data exclusivity of five years from the date of approval of data exclusivity for new chemical entities, and a period of data exclusivity of three years from the date of approval for supplemental applications, including clinical studies sponsored by the applicant that are essential to the approval. The first approved biologic may be subject to 12 years of exclusivity, but subsequent supplemental applications for the product will not accrue additional exclusivity without clinically meaningful changes to the structure of the product. Such periods can run irrespective of, but concurrent with, any patent term associated with the drug or treatment using the drug.

Other exclusivities are available for designated orphan drugs (seven years of market exclusivity), designated Qualified Infectious Disease Products (five years of additive exclusivity), 180 days (first generic applicant filing a patent certification), and satisfying paediatric study requests (six months of additive exclusivity).

There is no exclusivity framework for medical devices, and 510(k)-cleared devices may be designated as predicate devices immediately upon clearance. However, subsequent applicants for a class III device may not rely on data in PMA-approved medical device products.

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