

## **Arbitration in the Life Sciences/Biotech/Pharmaceutical/Medical Device Field**

Stephen P. Gilbert

*Abstract: Arbitration of disputes in the life sciences/biotech/pharmaceutical/medical device field is described, with a discussion of the possible advantages and drawbacks of arbitrating such disputes, identification of issues that may be of special interest when drafting an arbitration clause for the field, and examples of the use of arbitration in the field. Arbitration has been used in the life sciences/biotech/pharmaceutical/medical device field and can provide confidentiality (which is usually of paramount concern because of the intellectual property often involved in disputes in this field), the ability to choose decision-makers knowledgeable in the relevant field (e.g., licensing, patents), speed, the possibility of avoiding collateral estoppel in U.S. courts, the ability to deal efficiently with multi-national disputes, and cross-border enforcement (e.g., via the New York Convention).*

### **INTRODUCTION**

Unique features of arbitration make it advantageous for resolving all types of disputes in the life sciences/biotech/pharmaceutical/medical device field,<sup>1</sup> including disputes specific to the field, disputes that occur more often with STEM than non-STEM enterprises,<sup>2</sup> and disputes that can occur in most commercial settings.

The first category (disputes specific to the life sciences/biotech/pharmaceutical/medical device field) includes disputes concerning regulations of governmental agencies (e.g., FDA and FTC). Businesses in the field are STEM enterprises, and the second category (disputes that occur more often with STEM than non-STEM enterprises) includes disputes involving patents, trade secrets,

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<sup>1</sup> For ease of reference, life sciences, biotech (biotechnology), pharmaceuticals, and medical devices are lumped together as if they were a single field, which they are not, although they are related to each other and even overlap in some cases. Viewed at a high level, what they have in common is biology/physiology.

<sup>2</sup> “STEM” is science, technology, engineering, and mathematics.

know-how, and breach of contract (e.g., concerning R&D obligations).<sup>3</sup> The third category (disputes than can occur in most commercial settings) includes breach of contract disputes (e.g., breach of warranty, breach of confidentiality obligations, and failure to adequately market goods or make royalty payments), employment disputes, and trade regulation/competition/antitrust disputes.

No citation of authority is needed for the proposition that arbitration can be used for resolving breach of contract disputes, but it may not be immediately apparent that almost every type of commercial dispute between private parties can be arbitrated, including most, if not all, of the disputes likely to be encountered in the life sciences/biotech/pharmaceutical/medical device field.

Not that long ago, U.S. Courts said certain types of disputes, e.g., involving patents, could not be arbitrated. Patent law issues such as validity were said to be “inappropriate for arbitration proceedings and should be decided by a court of law, given the great public interest in challenging invalid patents.”<sup>4</sup> That was changed in 1983 by 35 U.S.C. § 294 (“Voluntary arbitration”), which provides for arbitration of “any dispute relating to patent validity or infringement.” Section 294 has been held to permit arbitration of inventorship disputes<sup>5</sup> even in an international setting.<sup>6</sup> In 1984, the patent statute was amended to permit arbitration of interferences, and the statute was further changed in 2013 when interferences were replaced with derivation proceedings (35 U.S.C. § 135(f)), which, broadly speaking, are for determining if the named inventor in a patent application derived the invention from someone else. In arbitration of validity, infringement, and derivation disputes, notice of the arbitral award must be received by the U.S. Patent and Trademark Office for the award to be enforceable, and the award is binding only on the parties to the arbitration, not on the general public.

The Federal Circuit has approved of arbitration in the patent area.<sup>7</sup> Trade secret disputes,<sup>8</sup> trademark disputes,<sup>9</sup> copyright disputes,<sup>10</sup> antitrust,<sup>11</sup> and other statutory claims<sup>12</sup> can be

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<sup>3</sup> Many STEM enterprise disputes directly or indirectly involve intellectual property, such as disputes concerning the creation, subsistence, validity, enforceability, ownership, licensing, assignment, scope, monetization, or violation of IP rights.

<sup>4</sup> *Beckman Instruments, Inc. v. Technical Development Corp.*, 433 F.2d 55, 63 (7 Cir. 1970).

<sup>5</sup> See, e.g., *Invista N. Am. S.A.R.L. v. Rhodia Polyamide Intermediates S.A.S.*, 503 F.Supp.2d 195 (D.D.C. 2007).

<sup>6</sup> *Concat LP v. Unilever, PLC*, 350 F.Supp.2d 796 (N.D. Cal. 2004).

<sup>7</sup> For example, in *Rhone-Poulenc Specialites Chimique v. SCM Corp.*, 769 F.2d 1569, 1572 (Fed. Cir. 1985), the Court held a patent license dispute had to be arbitrated, citing *Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc.*, 473 U.S. 614, 626 (1985), for the proposition that “as with any other contract, the parties’ intentions control, but those intentions are generously construed as to issues of arbitrability.”

<sup>8</sup> *Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 725 (9 Cir. 1999) (“Courts routinely refer claims for misappropriation of trade secrets to arbitration.”).

<sup>9</sup> *Gingiss International, Inc. v. Bormet*, 58 F.3d 328 (7 Cir. 1995).

arbitrated.<sup>13</sup> In short, virtually all commercial disputes in the life sciences/biotech/pharmaceutical/medical device field can be arbitrated. The question then becomes should they be.

## **CONSIDERATIONS IN DECIDING WHETHER TO ARBITRATE DISPUTES IN THE FIELD**

### **Advantages Of Arbitration**

Privacy/confidentiality, the possibility of avoiding having resolution of the dispute set a legal precedent (collateral estoppel), customization of the arbitration process, the ability to choose the decision-maker(s), achieving finality sooner, the likelihood of reduced cost, the ability to handle multi-national disputes, and worldwide enforcement of the arbitration award offer clear-cut advantages over litigation. Usually, at least several of those advantages will be realized in each arbitration being used to resolve a dispute in the field, particularly if the arbitration is held pursuant to an appropriate arbitration clause and the arbitrator is a “muscular” arbitrator (i.e., an experienced arbitrator determined to run, and with the skills to run, a fair and efficient proceeding).<sup>14</sup>

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<sup>10</sup> *LDS, Inc. v. Metro Canada Logistics, Inc.*, 28 F.Supp.2d 1297, 1301 (D. Kan. 1998) (“We find the language in the License Agreement mandating arbitration of ‘any controversy or claim arising out of or relating to this Agreement’ to be quite broad, and we note the absence of any express provision excluding copyright infringement disputes from arbitration.”).

<sup>11</sup> *Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 725 (9 Cir. 1999) (“Both the Supreme Court and this court have held that antitrust claims are arbitrable.”).

<sup>12</sup> *Gilmer v. Interstate/Johnson Lane Corp.*, 500 U.S. 20, 26 (1991) (internal brackets and quotation marks omitted):

It is by now clear that statutory claims may be the subject of an arbitration agreement, enforceable pursuant to the FAA. Indeed, in recent years we have held enforceable arbitration agreements relating to claims arising under the Sherman Act ...; § 10(b) of the Securities Exchange Act of 1934 ...; the civil provisions of the Racketeer Influenced and Corrupt Organizations Act (RICO) ...; and § 12(2) of the Securities Act of 1933 ....

Although all statutory claims may not be appropriate for arbitration, having made the bargain to arbitrate, the party should be held to it unless Congress itself has evinced an intention to preclude a waiver of judicial remedies for the statutory rights at issue.

<sup>13</sup> Some provider organizations even have specialized arbitration rules for IP disputes, e.g., CPR’s 2005 “Patent & Trade Secret Arbitration Rules” and the AAA’s 2006 “Resolution of Patent Disputes Supplementary Rules.”

More specifically, with respect to privacy/confidentiality, court proceedings are open to the public; arbitration proceedings are not—they are private. For obvious reasons, maintaining the confidentiality of intellectual property is often of paramount importance to parties in this field.

Resolving a dispute in a public forum provides many opportunities for confidentiality to be lost and the value of the intellectual property to be destroyed. However, if an appropriate confidentiality agreement is put in place for an arbitration (assuming the arbitration agreement and/or governing rules do not already mandate confidentiality), parties and counsel will be bound by non-disclosure provisions with respect to the entire proceeding, including the award (except for being able to disclose the award in court when moving to confirm or vacate the award). Furthermore, with a simple award (the award does not contain the reasons for the outcome and thus contains much less sensitive information than a reasoned award would), trade secret and other sensitive information (e.g., chemical process parameters for production of a pharmaceutical, identity of the supplier of the alloy used in a surgical device) can be kept from the public, even if the award becomes part of the public court record in a confirmation or vacatur proceeding.<sup>15</sup>

Requiring only a simple (rather than reasoned) award may also possibly keep a later tribunal from holding there was collateral estoppel based on the earlier arbitral award.<sup>16</sup> Thus, with a simple award, if there are two or more independent rationales the arbitrator could have used to reach her decision, there could not be any collateral estoppel.<sup>17</sup> For example, if an arbitrator held in a simple award that a party failed to prove the other side's liability for alleged trade secret misappropriation, that holding could be based on the arbitrator's belief that the information was not a trade secret or on the belief that although it might be a trade secret, misappropriation had not been proved. A later tribunal would not know which was the basis for the arbitrator's award,

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<sup>14</sup> How many of those advantages will be realized depends to a significant extent on the specific dispute being arbitrated and the actions of the parties. A party determined to delay and drive up cost can cause mischief, but even such a party may have difficulty destroying all of the advantages of arbitration, particularly with a muscular arbitrator. See The College of Commercial Arbitrators, *Protocols for Expeditious, Cost-Effective Commercial Arbitration* (2010), available at <https://www.ccaarbitration.org/resources/cca-protocols/> (last accessed June 23, 2017).

<sup>15</sup> See, e.g., AAA Commercial Rules, R-46(b): “The arbitrator need not render a reasoned award unless the parties request such an award in writing prior to appointment of the arbitrator or unless the arbitrator determines that a reasoned award is appropriate.”

<sup>16</sup> Collateral estoppel regarding an issue in a later action requires the issue be identical to an issue raised, necessarily decided, and material in the earlier action. In other words, the issue in question must have been actually decided in the earlier action and its determination must have been essential to the judgment (the party against whom the estoppel is asserted must also have had a full and fair opportunity in the earlier proceeding to litigate the issue). *B & B Hardware, Inc. v. Hargis Industries, Inc.*, 575 U.S.\_\_\_\_, 135 S.Ct. 1293, 1302-03 (2015) (applying collateral estoppel in the trademark area).

<sup>17</sup> *Postlewaite v. McGraw-Hill, Inc.*, 333 F.3d 42, 48-49 (2 Cir. 2003) (although collateral estoppel can be based on an arbitral award, no collateral estoppel here because there was more than one possible ground for the arbitral award, which did not state any ground for the decision).

and there could be no collateral estoppel as to whether the information was (or was not) a trade secret.

The arbitration process can be customized by the parties beyond just the type of award to be rendered, for example, to limit the types of claims/disputes that can be arbitrated (e.g., all claims relating to or arising under the patent license agreement are to be arbitrated except for claims of patent invalidity or unenforceability), to set requirements for selection of the arbitrator (e.g., a patent attorney who has arbitrated at least twenty cases to award and has a degree in chemistry or pharmacology), to limit discovery (e.g., documents only—no depositions, completion of discovery within three months from appointment of the arbitrator), to prohibit motions other than concerning discovery, to limit the number of witnesses to be called by each side to testify at the hearing, and to set a deadline for rendering the award (e.g., award to be rendered within six months of appointment of the panel). In a lawsuit, parties have little or no control over any of these parameters.

As an example of customization of the process, in an arbitration to determine whether a multi-million dollar annual minimum royalty for a license to make and sell a prescription drug under development was owing and payable, the parties set a four-month time limit from the appointment of the arbitration panel to issuance of the award. Because of the self-imposed compressed schedule, the case was conducted with virtually no discovery and with only three hearing days; briefing and the reasoned award were of necessity tightly focused.<sup>18</sup>

Selection of the arbitrator is one of the most important decisions—if not the most important—to be made by parties to an arbitration. Thus, the parties should select arbitrators having excellent process skills and should consider whether to select arbitrators knowledgeable in the relevant field.<sup>19</sup> The desired qualifications may often be found in one person, but sometimes it may be difficult to find an experienced arbitrator who has expertise in a particular field. For example, in an arbitration to determine whether an FDA consulting organization committed malpractice during its professional engagement by a foreign company to help it obtain FDA approval for sale of a medical device in the U.S., the chair and one of the wing panelists were lawyers and experienced arbitrators, the chair also had substantial science/engineering training and

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<sup>18</sup> As another example, in an arbitration where the sole issue to be decided was whether certain software was a Licensed Product under a patent license agreement (i.e., whether the claims of the licensed patent covered the software and its process), the parties agreed: there would be no discovery, each side could call only one witness (a technical expert) at the evidentiary hearing, the damages (i.e., unpaid royalties) if the software were held to be a Licensed Product were stipulated, and the award would be a simple award.

<sup>19</sup> The parties risk losing many of the benefits of arbitration if the arbitrator does not have excellent process skills. For example, an arbitrator should be able to persuade parties that even though the arbitration agreement allows discovery under the Federal Rules of Civil Procedure (as some do), each side should start with two depositions (and with a time limit on each), rather than the ten (with no time limit) being requested by each side, and come back to the arbitrator if good cause can be shown for agreeing to more depositions.

experience, and the second wing panelist had less arbitration experience but was a medical doctor and long-time consultant to the FDA.<sup>20</sup>

For a given commercial dispute, arbitration will almost always be faster than litigation and will usually provide finality substantially sooner than litigation. Aside from time limits set by the parties or by the governing rules, a muscular arbitrator will move the process along (e.g., by controlling discovery and by prohibiting the making of substantive motions without prior approval, which will not be given unless certain criteria are met<sup>21</sup>). There are only limited grounds for vacating an award (see, e.g., 9 USC § 10(a)), and a careful arbitrator is not likely to provide the basis for any of them.<sup>22</sup> Under the Federal Arbitration Act (9 U.S.C. § 1 et seq.), a party must move to confirm an award within a year after the award is made, and notice of a motion to vacate, modify, or correct an award must be served within three months after the award is filed or delivered.<sup>23</sup> The percentage of awards challenged is small and not more than about 20% of those challenged are vacated.<sup>24</sup> Courts often deal quickly with proceeding to confirm or vacate awards. Thus, most arbitration awards will not be in court, not more than about a fifth of those challenged will be set aside, and Courts will often move quickly in such proceedings. Therefore, finality will usually be achieved substantially sooner than if the dispute had been litigated.

The cost of both arbitration and litigation has increased over the years, but arbitration can still be cheaper than litigation. In a typical commercial arbitration, the cost of the arbitrator and any administering arbitral institution is usually less than about 10% of the cost of counsel. Although that can still be substantial in a dispute in the life sciences/biotech/pharmaceutical/medical device field, a muscular arbitrator can control discovery and motion practice in a way that a court usually does not, thereby saving more in attorneys' fees than the cost of the arbitrator and any administering institution.<sup>25</sup> Furthermore, the narrower grounds for setting aside an arbitral award

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<sup>20</sup> The ability to select the arbitrator also obviates the need to worry about how a lay judge or jury will deal with even the smallest amount of technical evidence.

<sup>21</sup> See, e.g., AAA Commercial Arbitration Rule R-33 (Dispositive Motions): “The arbitrator *may* allow the filing of and make rulings upon a dispositive motion *only if* the arbitrator determines that the moving party has shown that the motion is likely to succeed and dispose of or narrow the issues in the case” (emphasis added).

<sup>22</sup> *Ramos-Santiago v. United Parcel Service*, 524 F.3d 120, 123 (1 Cir. 2008) (“[F]ederal court’s review of an arbitrator’s decision ... is extremely narrow and exceedingly deferential”) (internal quotation marks omitted).

<sup>23</sup> 9 U.S.C. §§ 9 & 12.

<sup>24</sup> See, e.g., Mills et al., “Vacating Arbitration Awards,” *Dispute Resolution Magazine*, pp. 23-27 (Summer 2005) (roughly 20% of awards vacated); and Mills et al., “Exceeding Powers’: Exploring Recent Trends In Cases Challenging Tribunal Authority,” AAA Program March 20, 2014 (similar). See <https://www.aaau.org/media/20038/supplemental%20materials.pdf> (last accessed June 23, 2017).

than for appealing a trial court judgment often make any post-award proceedings less expensive than post-judgment proceedings.

Disputes in the life sciences/biotech/pharmaceutical/medical device field often cross national borders (e.g., those involving intellectual property or licensing), and it is not uncommon for a worldwide agreement (e.g., a trade secret license) to specify that any disputes (even if multi-national) will be handled in a single arbitration. Thus, for example, a claim that a licensee has not made adequate royalty payments for sales of a licensed product in several countries would be heard by just one panel located in just one country. That obviously allows certain efficiencies.

As to the advantage of worldwide enforcement of arbitral awards, the U.S. is signatory to treaties that allow such enforcement, e.g., the “New York Convention” (1958 Convention on the Recognition and Enforcement of Foreign Arbitral Awards<sup>26</sup>) and the “Panama Convention” (the 1975 Inter-American Convention on International Commercial Arbitration<sup>27</sup>). Thus, the New York Convention allows a party to bring an arbitral award from any first country that adheres to the New York Convention (e.g., the U.S.) to the courts of any second country that also adheres to the New York Convention (e.g., France) and have it enforced by those courts; approximately 156 countries are signatories. In contrast, there are no treaties that allow judgments of U.S. courts to be readily enforced in other countries.<sup>28</sup> The grounds for a second country to refuse enforcement of an award from a first country are limited, e.g., the arbitration agreement was not valid, the arbitration procedure was not in accordance with the agreement of the parties, enforcement of the award in the second country is contrary to its public policy (see Article V of the 1958 “Convention On The Recognition And Enforcement Of Foreign Arbitral Awards”).<sup>29</sup>

Being able to readily enforce an award from one country in a second country saves time and expense as compared to having to start a new merits proceeding in the second (and third, and fourth, etc.) country. Therefore, e.g., a claimant who received an award in one country in its favor holding that the respondent had misappropriated claimant’s trade secret concerning

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<sup>25</sup> The author of a thoughtful article comparing arbitration and litigation notes that “arbitration is not necessarily less expensive than litigation” but that “the real cost savings in arbitration lies in the likelihood that an arbitrator will be less inclined than a judge to entertain extensive discovery and motions practice, both of which frequently drive the fees and costs of litigation.” Freeman, “Litigation: Arbitration v. litigation,” *Inside Counsel* (April 19, 2012). See <http://www.insidecounsel.com/2012/04/19/litigation-arbitration-v-litigation> (last accessed June 23, 2017).

<sup>26</sup> Implemented in 9 U.S.C. Chapter 2.

<sup>27</sup> Implemented in 9 U.S.C. Chapter 3.

<sup>28</sup> As noted by the U.S. Department of State: “There is no bilateral treaty or multilateral convention in force between the United States and any other country on reciprocal recognition and enforcement of judgments.” <https://travel.state.gov/content/travel/en/legal-considerations/judicial/enforcement-of-judgments.html> (last accessed June 23, 2017).

<sup>29</sup> [https://treaties.un.org/doc/Treaties/1959/06/19590607%2009-35%20PM/Ch\\_XXII\\_01p.pdf](https://treaties.un.org/doc/Treaties/1959/06/19590607%2009-35%20PM/Ch_XXII_01p.pdf) (last accessed June 23, 2017).

production of monoclonal antibodies could bring the award to a second country for enforcement without having to commence a proceeding in the second country in which it would have to prove the existence and misappropriation of the trade secret.

### **Possible Drawbacks Of Arbitration**

Unless provided for by the governing rules or agreement to arbitrate, there is no true appeal of an arbitration award, i.e., a review on the merits. As noted above, a court's review of an arbitration award occurs during a confirmation or vacatur proceeding but is on limited grounds (see footnote 22, above). In practice, there are few arbitration appeals, even if the governing rules or agreement to arbitrate allow an appeal on the merits. Nevertheless, some parties are reluctant to relinquish the right to a merits appeal in court.

If a disputant believes it will win *and* wants to set a public, legal precedent, a lawsuit will likely be preferable to arbitration, because of the private (and also possibly confidential) nature of arbitration and because with rare exception, arbitral awards are not publicly available or published in any reporter, so third parties cannot find and be guided by them.

Depending on the particular dispute, other factors may make arbitration problematic, e.g.: (i) is there is a third party that cannot be brought into the arbitration but whose presence is needed to afford complete relief or reduce/eliminate the possibility of inconsistent results from different tribunals (e.g., the manufacturer of a reagent used in a clinical assay where there is a dispute between a licensor and licensee regarding whether incorporation of the third-party reagent into the assay kit sold under license is permitted, and the licensor believes the manufacturing process for making the reagent may be infringing its patent), or (ii) is evidence needed from a third party that likely will not voluntarily provide it and that is not subject to an arbitral subpoena to attend the main evidentiary hearing (e.g., the manufacturer of the controlled-release matrix used in an orally administered dosage form).

### **BALANCING THE PROS AND CONS OF ARBITRATION**

When deciding whether to include an arbitration clause in a contract in the life sciences/biotech/pharmaceutical/medical device field or whether to suggest arbitration (when there is no arbitration clause), there is no one-size-fits-all answer. One or more factors such as the ability to choose the decision-maker (e.g., a muscular arbitrator knowledgeable in the relevant technology), privacy/confidentiality (e.g., to protect trade secrets), customization of the process (e.g., setting deadlines, limiting discovery, and possibly avoiding collateral estoppel), the likely substantially reduced time to finality, the possibly reduced cost, the ability to handle cross-border disputes, and worldwide enforcement of the award will often outweigh factors such as the perceived need for a full right of appeal on the merits, the possible difficulty in joining third parties or obtaining evidence from them (if either is needed), the perceived need to set a public, legal precedent, and the possibility that the cost will, in fact, not be less than that for litigation. That said, the sometimes arcane law (e.g., patent law) and the complexity, technical subject matter, and value of intellectual property in the field make arbitration a good choice for resolution of many disputes if executive discussions and mediation do not work.



## **ARBITRATION HAS BEEN USED IN THE FIELD**

Arbitration has been used in the life sciences/biotech/pharmaceutical/medical device field over the years in a variety of settings, e.g.:

- *Rhone-Poulenc Specialites Chimique v. SCM Corp.*, 769 F.2d 1569 (Fed. Cir. 1985) (court ordered arbitration involving scope, validity, and infringement of a patent concerning a geraniol product (an insect repellent) to proceed);
- *Generica Limited v. Pharmaceutical Basics, Inc.*, 125 F.3d 1123 (7 Cir. 1997) (affirming district court's confirmation under the New York Convention of a foreign award for breach of an agreement to develop, obtain FDA approval for, manufacture, and market clomiphene citrate (Clomid), an infertility drug);
- *Infinity Industries, Inc. v. Rexall Sundown, Inc.*, 71 F.Supp.2d 168, 172 (E.D.N.Y. 1999) (court ordered parties to arbitration concerning supply contract for St. John's Wort, notwithstanding argument there was "no established tradition of arbitration in the pharmaceutical industry");
- *Baxter International, Inc. v. Abbott Laboratories*, 315 F.3d 829 (7 Cir. 2003) (court affirmed judgment upholding arbitral award concerning manufacture and sale of sevoflurane, an anesthetic, which award held there was no violation of antitrust laws);
- *Affymax, Inc. v. Johnson & Johnson*, 420 F.Supp.2d 876 (N.D. Ill. 2006) (court stayed litigation, ordered parties to arbitrate inventorship and ownership of a patent concerning peptide drugs, and enjoined further litigation in Germany); and
- *Promega Corp. v. Life Technologies Corp.*, 674 F.3d 1352, 1356 (Fed. Cir. 2012) (court affirmed judgment ordering parties to arbitrate licensing dispute (underpayment of royalties) involving patents concerning genetic identification).

## **CONSIDERATIONS IN DRAFTING AN ARBITRATION CLAUSE FOR THE FIELD**

When drafting an arbitration clause in the life sciences/biotech/pharmaceutical/medical device field, it may be advantageous to deal with certain issues beyond the ones typically enumerated, those being whether an arbitral institution will administer the arbitration, the governing set of rules, number of arbitrators, seat/location of arbitration, right to enforce the award in any court of competent jurisdiction, law governing the arbitration process (e.g., Federal Arbitration Act), allowable remedies (e.g., whether the arbitrator can or cannot award punitive and/or consequential damages), and apportioning costs of the arbitration and attorneys' fees.

Additional issues to consider for arbitrations in the field include whether all disputes are to be arbitrated (e.g., "all disputes arising out of and/or relating to this R&D agreement") or whether there are to be any carve-outs (e.g., "all disputes arising out of and/or relating to this license agreement other than patent validity and enforceability"), a requirement for confidentiality on the part of all parties and attorneys, and the qualifications of the arbitrator (e.g., an attorney who was a partner in a major law firm for at least ten years, who has conducted at least ten arbitrations to award, and who has a degree in biology, bioengineering, chemistry, or chemical engineering).

Arbitration clauses sometimes impose deadlines (e.g., five months for rendering the award from the time the arbitrator is appointed), but that may place an impossible burden on everyone

involved. No limits or limits on discovery may also be problematic (no limits, e.g., full discovery under the Federal Rules of Civil Procedure, may result in delay and additional cost; stringent limits, e.g., only one deposition per side for not more than four hours, may severely restrict counsel in a difficult case). Limiting the length of the hearing (e.g., 10 hours per side) may make it almost impossible for one party to prove certain types of claims (e.g., infringement of a complex surgical device patent) or for the other party to prove its defenses (e.g., invalidity of that patent). Thus, in the life sciences/biotech/pharmaceutical/medical device field, tight deadlines and tight time limits may be inadvisable because of the likely complexity of many disputes.

Finally, consideration should be given to using step clauses in the field for dispute resolution, where arbitration is the final step if discussion among executives of the parties and then mediation (each with a time limit, e.g., 30 days) do not resolve the matter.

## **CONCLUSION**

Arbitration has been used in the life sciences/biotech/pharmaceutical/medical device field. Arbitration can provide confidentiality, the ability to choose decision-makers knowledgeable in the relevant areas, speed, the possibility of avoiding collateral estoppel in U.S. courts, the ability to deal efficiently with multi-national disputes, and cross-border enforcement, which often outweigh factors such as the perceived need for a full right of appeal on the merits, the possible difficulty in joining third parties or obtaining evidence from them (if either is needed), any perceived need to set a public, legal precedent, and the possibility that the cost of arbitration will, in fact, not be substantially less than that for litigation. There is no one-size-fits-all choice for all disputes.

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*Stephen P. Gilbert is a full-time arbitrator and mediator and a Fellow of the College of Commercial Arbitrators, of the Chartered Institute of Arbitrators, and of the American College of e-Neutrals, as well as a Member/Panelist of the Silicon Valley Arbitration & Mediation Center, an American Arbitration Association Commercial Master Mediator, and a CEDR Accredited Mediator. From 1988 to 2010, he was a partner in a major multi-national law firm, the last three years as Co-Leader of its IP practice group, and before working as a patent, trademark, and copyright attorney, he was a computer programmer, a chemical process engineer, and a consulting engineer. His website is [www.spgadr.com](http://www.spgadr.com) and his email is [spgadr@msn.com](mailto:spgadr@msn.com).*

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