

Biotechnology Sellers Beware: The Risks and Opportunities of Doing Business with the Government

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FOR BIOTECHNOLOGY COMPANIES, the escalating requirements for homeland security have uncorked a burgeoning demand by the United States Government for research, products, and services to combat bioterrorism. The Government's needs range from vaccines to detection devices to decontamination agents for defending against biological and chemical warfare. In December 2001, Congress doubled spending for bioterrorism research.¹ For 2003, the President's budget includes \$5.9 billion for defending against the threat of bioterrorism, an increase of \$4.5 billion—319 percent—over the 2002 funding level.² By 2005, bioterrorism research and development funding to the biotechnology and pharmaceutical industries has been projected as high as \$50 billion.³

However, with these opportunities come substantial risks and costs. As the largest buyer in the world, the United States Government acquires more than \$230 billion of goods and services each year.⁴ With its monolithic buying power, the Government imposes a labyrinth of arcane, overlapping, and sometimes conflicting requirements on companies seeking such business. Indeed, Government contractors must tread carefully through a procurement minefield laden with more than 3000 statutes and countless regulations governing everything from bidding procedures and accounting practices to socioeconomic responsibilities (e.g., clean water and air, affirmative action, and labor standards) and ethical requirements (e.g., kickbacks, gratuities, and conflicts of interest).⁵

For those who deal with the Government, shortcuts are not an option, as the Supreme Court warned

long ago: "Men must turn square corners when they deal with the Government."⁶ For contractors who fail to "turn square corners," the Government has an army of more than 20,000 lawyers and a fistful of remedies, including criminal sanctions, civil fraud penalties, and mandatory contract clauses for enforcing these many requirements. The risk is particularly acute for those who, like many in the biotechnology industry, are not seasoned in Government contracting requirements.

How can these risks be recognized? An encyclopedic list of such risks would defeat the attention span of most of the sane population. However, the discussion below captures many of the key risks as they arise in the lifecycle of a Government contract: (1) finding contracts; (2) getting contracts; (3) performing contracts; and (4) protecting contract rights.

FINDING CONTRACTS

The contracts are out there. The Centers for Disease Control and Prevention (CDC) and the De-

¹ Jeff Donn, *Qualms Grow With Bioterror Research*, AP ONLINE, Jan. 27, 2002.

² Office of the Press Secretary Fact Sheet, *Defending Against Biological Terrorism*, p. 1 (Feb. 5, 2002) (<http://www.whitehouse.gov/news/releases/2002/02>).

³ Julie Appleby and Edward Iwata, *Biotech Firms Put Focus on Military, Defense Efforts*, *USA Today*, p. 3B (Nov. 15, 2001).

⁴ See Fiscal Year 2001 Federal Procurement Data System, pp. 2, 42 (www.fpdc.gov).

⁵ See Fiscal Year 2001–2005 Procurement Executives Council Strategic Plan, Appendix C, p. 24 (www.pec.gov).

⁶ *Rock Island, Arkansas & Louisiana Railroad Co. v. United States*, 254 U.S. 141, 143 (1920). See also, *United States v. Smoler Bros., Inc.*, 95 F. Supp. 676, 679 (E.D. Ill. 1949), affirmed in part and reversed in part by *United States v. Smoler Bros., Inc.*, 187 F.2d 29, 1951 (7th Cir. Ill. 1951) (liquidated damages assessed under Walsh-Healey Public Contracts Act for violation of labor standards).

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partment of Health and Human Services (DHHS) have awarded Acambis PLC contracts worth about \$771 million to deliver 209 million doses of smallpox vaccine for civilian use.⁷ In October 2002, the National Institute of Allergies and Infectious Diseases announced that it had awarded to two companies contracts designed to spur development of a new anthrax vaccine, with a combined contract value of \$22.5 million through 2003.⁸ In 2004, the DHHS will award larger competitive contracts to companies for the manufacture and maintenance of a 25-million dose emergency stockpile of anthrax vaccine.⁹ The Department of Defense (DoD) has awarded similar contracts for combating smallpox and anthrax.¹⁰

In addition to these examples, a host of other biotechnology products are in the pipeline:

- Decontamination foam for neutralizing biological and biochemical agents such as nerve and mustard gas.¹¹
- Inexpensive anthrax test kits and antidotes.¹²
- Protein badges for detecting a broad spectrum of pathogens to protect first-response officers from biological threats.¹³
- Bioinformatic programs capable of tracing a biological agent's genetic lineage back to its source.¹⁴
- Laser beam applications for killing bacteria and viruses.¹⁵

Finding contract opportunities for all of these promising technologies may come with a variety of hurdles for many firms. Navigating the complex network of Government entities to find the agency in charge of research, development, procurement, and policy with respect to a particular biodefense technology presents a considerable challenge in today's environment. Despite the establishment of the Department of Homeland Security, responsibility for funding of anti-terrorism initiatives continues to be fragmented among a number of agencies, with the divide between civilian and military applications being particularly acute.¹⁶ Even with increased funding for fighting terrorism, many agencies are facing too many good ideas chasing too few dollars. For example, the DoD's request to industry in October 2001 for anti-terrorism concepts and proposals generated more than 12,000 responses through which the department is still wading.¹⁷ While initial research and development funding is often available

for biodefense products, conflicts between agencies and the delay inherent in Government decision-making may mean that the additional, substantial funds required to develop and obtain regulatory approval for a product such as an anthrax vaccine cannot be obtained in a timely manner. Further, without a commitment by the Government to purchase the product, public and private capital may not be available to continue development.

Nonetheless, potential Government contractors have a number of resources at their disposal for locating business opportunities. First, nearly all potential contracts over \$25,000 must be publicized on the Internet at www.fedbizopps.gov.¹⁸ However, some opportunities for combating bioterrorism may not be publicized because of national security concerns, urgency necessitating expedited procurement, or certain acquisitions from small businesses.¹⁹ Second, for firms with biotechnology products having commercial applications, the General Services Administration (GSA) may offer a source for selling services and products on the Federal Supply Schedule. Much like a buying catalog for federal agencies, the Federal Supply Schedule lists various commercial items and services at specified prices, allowing agencies to place orders quickly and efficiently for the listed items.²⁰

⁷ Of Terrorists and Mosquitoes, *Washington Post*, p. E1 (Nov. 5, 2002).

⁸ NIH Is Funding New Generation of Anthrax Vaccine, *Wall Street Journal*, p. B4 (Oct. 4, 2002).

⁹ *Id.*

¹⁰ Biodefense firm extends anthrax contract, *Washington Bus. J.*, p. 10 (Aug. 9, 2002).

¹¹ Edward Iwata, Techies Answer USA's Call to Arms, *USA Today*, p. 1B (Oct. 30, 2001).

¹² Richard Simon, Response to Terror; Inventions; Some Companies Find Opportunity for Profit in War on Terror, *Los Angeles Times*, p. A14 (Oct. 28, 2001).

¹³ Donna Daley, Area Companies Gear Up to Fight Terror, *Telegram & Gazette*, p. F8 (Feb. 22, 2002).

¹⁴ Alex Sivitz *et al.*, Forecasting 2002, *Washington Techway*, p. 34(4) (Dec. 10, 2001).

¹⁵ Julie Appleby and Edward Iwata, Biotech Firms Put Focus on Military, Defense Efforts, *USA Today*, p. 3B (Nov. 15, 2001).

¹⁶ Deirdre Davidson, Lobbyists Find Safety a Hard Sell, *Legal Times*, pp. 1, 20 (Aug. 12, 2002).

¹⁷ *Id.*, p. 20.

¹⁸ Federal Acquisition Regulation (FAR) § 5.201(d)(1).

¹⁹ FAR § 5.202(a)(1), (2), (4) and (7).

²⁰ FAR § 38.101. See www.gsa.gov for information on Federal Supply Schedule opportunities and the process for getting on the GSA schedule.

Furthermore, some firms may prefer to create their own opportunities. For companies with political clout and access, Congressional committees have been known to include specific funds directed to a specific firm or technology.²¹ However, a strategy with a higher likelihood of success may be an unsolicited proposal. For such proposals, the Federal Acquisition Regulation (FAR) states: Unsolicited proposals allow unique and innovative ideas or approaches that have been developed outside the Government to be made available to Government agencies for use in accomplishment of their missions.²²

Many biotechnology products may fit the “unsolicited proposal” requirements for being “innovative and unique” and “independently originated” outside the Government. However, timing is critical as an unsolicited proposal—to be valid—must be submitted *before* the Government issues a solicitation or otherwise makes its requirement known for the particular product or service.²³

GETTING CONTRACTS

Once a prospective contract opportunity is identified, the next—and more challenging—step is to pursue and land the contract. At this juncture, a firm seeking business faces a host of legal and financial risks specifically associated with getting Government contracts. These risks fall roughly into the following categories: (1) marketing; (2) teaming; (3) proposal development and submission; and (4) protests.

Marketing risks

How does a company market its products: (1) entertain the prospective buyer with meals and gifts? (2) obtain inside information about competitors and the buyer? or (3) hire former employees of the buyer? While some of these practices may pass muster in the commercial marketplace, they may spell big trouble when doing business with the Government.

Gifts and Gratuities. Gifts to Government employees raise a quick red flag. For example, one statute makes gratuities to Government personnel a crime, while another statute and regulation allow the Government to terminate contracts flowing from such gratuities.²⁴ Except for items of nominal value (e.g., pens or plaques), gratuities cover a broad range of benefits, including cash, liquor, clothing, and paid vacations.²⁵

Inside Information. In the commercial marketplace, inside information about a buyer or competitor may render a decisive marketing advantage (or spark trade secret litigation). In the Government marketplace, having inside information about the Government’s selection process or a competitor’s confidential data may disqualify a company from the competition or result in termination of any contract tainted by such inside information.²⁶ Accordingly, Government contractors must beware of receiving any confidential information about a competitor’s proposal or the Government’s selection process in the course of competing for a Government contract.

Former Government Employees. Hiring a former employee of a buyer may not only provide critical expertise but also offer unique insights into buying practices and strategies of the customer. However, hiring away the chief scientist of a major pharmaceutical company is quite different from employing the chief scientist at NIH or CDC. A maze of conflict of interest statutes and regulations limit the types of matters on which former Government employees may work and when (if ever) they may be hired for certain tasks.²⁷ Furthermore, if the former Government employee has been involved in an ongoing competition that includes the new employer, the risk of being disqualified from the competition is considerable.²⁸

²¹ See, e.g., Deirdre Davidson, Lobbyists Find Safety a Hard Sell, *Legal Times*, p. 20 (Aug. 12, 2002) (Treasury appropriations bill would direct funding for anti-counterfeiting technology); *AUTOFLEX, Inc.*, B-240012, 90-2 CPD ¶ 294 (statute limited procurement to original equipment manufacturers); FAR § 6-302-5 (authorizing non-competitive awards as mandated by statute).

²² FAR § 15.603(a).

²³ FAR § 15.603(a)(5). For detailed guidance for the preparation and submission of unsolicited proposals, see FAR §§ 15.604 and 15.605.

²⁴ See 18 U.S.C. § 201(c) (criminal statute relating to gratuities); 10 U.S.C. § 2207 (Department of Defense statute authorizing contract termination for gratuities); FAR Subpart 3.2.

²⁵ See 5 C.F.R. § 2635; *United States v. Romano*, 583 F.2d 1 (1st Cir. 1978 (gratuities included cash, meat, liquor, and clothing)).

²⁶ The Procurement Integrity provisions appear in 41 U.S.C. § 423 and FAR § 3.104.

²⁷ See, e.g., 18 U.S.C. § 207 (criminal conflict of interest provisions); 41 U.S.C. § 423(d) (restrictions upon certain program and contracting officials); 5 CFR §§ 2635, 2637 and 2641.

²⁸ See, e.g., *NKF Eng’g, Inc. v. United States*, 805 F.2d 372 (Fed. Cir. 1986) (contractor disqualified from competition after hiring former Navy employee who was substantially involved in the acquisition process).

What can be done to mitigate these risks? For many Government contractors, a combination of training and written procedures on standards of conduct and ethics serve to alert employees of such risks. Furthermore, the hiring process for former Government employees requires additional screening during the interview process and controls on what work may be assigned, consistent with the conflict of interest rules.

Teaming risks

For many biotechnology companies, collaborating with other firms is a way of life for researching, developing, and commercializing products. As a result, many of the issues arising from such collaborations (such as protection of trade secrets, allocation of management responsibilities, or termination rights) are already well understood. Nonetheless, the Government contracting process still manages to heighten the risk in certain areas.

Disgruntled Teammates. Unhappy teammates can exist under any arrangement, but the risk of liability for failed Government contract teaming agreements has expanded significantly in recent years. For example, some courts have allowed former teammates to pursue litigation for alleged breaches even in the absence of an executed subcontract²⁹ or a final written agreement.³⁰ Not all courts have opened the door to teammate litigation, but this risk should be weighed in the course of negotiating teaming agreements.³¹

Antitrust Implications. On several occasions, the DoD has taken the position that exclusive teaming agreements are anticompetitive.³² While the department has recently backed off from this position,³³ teaming agreements that “eliminate competition” must be reported under the current regulations³⁴ and may expose the teammates to antitrust investigations and possible lawsuits.

Kickbacks. If a business relationship ripens into a subcontract, the deal better not have resulted from a kickback. The classic kickback arises when a subcontractor employee gives money or some other desirable “gift” to a prime contractor employee in return for a subcontract award. Given that such conduct can trigger both criminal and civil penalties,³⁵ Government contractors should have controls and documentation requirements in place for subcontracts to lessen the likelihood of rogue subcontracting personnel

getting away with improper side deals and subcontract awards.

Proposal risks

If a Government contractor did not have to submit certifications, prices, and resumes during the proposal process, the risk of doing business with the United States would be greatly reduced. Such is not the case. As a result, biotechnology firms entering the Government arena must take care any time that they make representations or offer prices to the Government.

Certifications and Representations. For the uninitiated, typical Government requests for proposals (RFPs) contain a bewildering mix of mandatory certifications and representations that must be made with the offeror’s proposal. Examples include lobbying payments (FAR § 52.203-11), debarment status (FAR § 52.209-5), place of performance (FAR § 52-215-6), small and disadvantaged business status (FAR § 52.219), child labor (FAR § 52.222-18), equal employment opportunity (FAR § 52.222-22), affirmative action compliance (FAR § 52.222-25), recycled materials (FAR § 52.223-4), toxic chemical release (FAR § 52.223-13), Buy American (FAR § 52.225-2), and plenty more. For procurements for items that are commercially available (rather than items produced specifically for the Government), the list is much shorter (FAR § 52.212-3) but still burdensome and fraught with risk.

In the commercial world, an inaccurate certification may cost the seller a customer. On the Government contract battlefield, an inaccurate certification can ignite a devastating barrage of criminal false statements (18 U.S.C. § 1001), civil fraud (31 U.S.C. §§ 3729-33), and specific administrative remedies all fired in tandem. For criminal and civil

²⁹ *ATACS Corp. v. Transworld Communications, Inc.*, 155 F.3d 659 (3d Cir. 1998).

³⁰ *Cable & Computer Technology v. Lockheed Sanders, Inc.*, 214 F.3d 1030 (9th Cir. 2000).

³¹ *W. J. Schafer & Associates, Inc. v. Cordant, Inc.*, 254 VA 514 (1997).

³² See, e.g., 66 Fed. Reg. 55157 (Nov. 1, 2001); Undersecretary of Defense Jacques Gansler’s memorandum to defense agencies (Jan. 5, 1999).

³³ 67 Fed. Reg. 18160 (Apr. 15, 2002).

³⁴ FAR § 3.301.

³⁵ For a summary of kickback restrictions and penalties, see FAR § 3-502-2.

fraud, the ostrich defense (i.e., deliberate ignorance or “I know nothing” defense) rarely works, as a contractor must generally exercise some due diligence to ascertain whether a certification is accurate prior to making it.³⁶ Short of fraud, inaccurate certifications have also spawned administrative actions by the Government to revoke acceptance of goods and civil actions by competitors claiming injury as a consequence of certification errors.³⁷ For all of these reasons, Government contractors have ample incentive to establish systems and controls to assist in assessing the accuracy of certifications and representation in proposals.

Resumes and Key Personnel. For biotechnology companies perhaps more than in other industries, a company’s personnel represent a key asset and a big part of how the company promotes itself to potential customers. Not surprisingly, the Government often requests resumes of key personnel in competitions for research and development contracts. While inaccurate resumes in the athletic world have cost some coaches their high-profile jobs, similar inaccuracies in Government contract procurements have triggered investigations and allegations of making false claims, which carry the attendant risk of treble damages, penalties, and contract termination. As with certifications, companies have a real incentive to check out resumes prior to submission to the Government.

As another risk, some Government solicitations require companies to list key personnel for performing the contract. If a company proposes one set of personnel with the intent of substituting an entirely different team for performance, such practices have been rejected as a classic “bait and switch” tactic.³⁸ Accordingly, a company must be ready to explain—and perhaps even defend—any changes in key personnel occurring between the proposal and the resulting contract.

Pricing Risks. By law, the Government cannot evaluate proposals without considering price or cost.³⁹ Under some circumstances, the company must submit supporting cost data and perhaps even certifications relating to such data.⁴⁰ For inaccurate, incomplete, or outdated cost data, the Government may have an administrative remedy to reduce the price of any resulting contract.⁴¹ In some cases, the submission of false or bogus cost data to inflate the contract price has resulted in findings of criminal and civil fraud.⁴² To minimize such risks, contractors should have procedures and controls in place to

catch defective cost or pricing information before it reaches the Government.

Protests

For commercial procurements, an award usually ends the effort to get the contract. Not so for Government acquisitions. Instead, the losers have a right to protest the Government’s award to the winner.⁴³ Thus, the joy of winning may be suddenly displaced by the delayed revenues secondary to suspended performance pending resolution of the protest, the cost of defending against the protest, and the risk of the original award decision being overturned. On the flip side, the protest offers the disappointed bidder the hope that the award decision will be turned around, although the agency usually wins in the end. In the spectrum of least to most formal and costly, the protester has the options of filing the protest with the agency itself, the General Accounting Office (GAO), or the Court of Federal Claims. Although most contract awards do not result in protests, the likelihood often increases with contract size, as well as the strategic importance of the contract to the particular company and market segment. Accordingly, biotechnology companies bidding for government contracts should be aware of, and generally prepared for, the range of protest possibilities.

³⁶ For criminal fraud cases involving “reckless disregard for the truth” and “deliberate ignorance,” see *United States v. Cook*, 586 F.2d 572, 579 (5th Cir. 1978) (false claim, 18 U.S.C. § 287); *United States v. Evans*, 559 F.2d 244, 246 (5th Cir. 1977). For civil fraud actions involving the “reckless disregard” standard, see 31 U.S.C. § 3729(b)(2); *United States v. Co-operative Grain and Supply Co.*, 476 F.2d 47, 60 (8th Cir. 1973).

³⁷ See *Boston Pneumatics, Inc.*, GSBCA No. 3122, 72-2 BCA ¶ 9682 (Government revoked acceptance for goods that had been inaccurately certified as compliant); *Iconco v. Jensen Construction Co.*, 622 F.2d 1291, 1302 (8th Cir. 1980) (unjust enrichment claim by disappointed bidder against contractor that inaccurately certified its status as a small business while competing for a Government contract).

³⁸ See *ManTech Advanced Systems Int’l, Inc.*, B-255719.2, 94-1 CPD ¶ 326; *Informatics, Inc.*, B-188566, 57 Comp. Gen. 217 (1978).

³⁹ 10 U.S.C. § 2305(a)(2)(A); FAR § 15.304(c)(1); *Boeing Sikorsky Aircraft Support*, B-277263.2, 97-2 CPD ¶ 91 at 9-10.

⁴⁰ FAR § 15.403-4.

⁴¹ See, e.g., FAR §§ 52.215-10, 52-215-11, and 52-215-20.

⁴² See, e.g., *United States v. Poarch*, 878 F.2d 1355 (11th Cir. 1989) (criminal false statement based upon inflated labor hours and concealed labor hour data); *United States v. Foster Wheeler Corp.*, 447 F.2d 100 (2nd Cir. 1971) (civil fraud for submission of defective cost data).

⁴³ FAR §§ 33.103 and 33.104.

PERFORMING THE CONTRACT

To be sure, a biotechnology company that survives the gauntlet of getting a Government contract has made significant strides. At the same time, the company faces a new and different set of risks related to performing the contract. Some of the more troublesome risks unique to Government contracts include those associated with (1) funding, (2) accounting and cost, (3) product and quality, (4) third-party liability, and (5) changes in the work to be done.

Funding risks

In the commercial world, no buyer would be so bold as to refuse payment because Congress had yet to appropriate sufficient funding. Government contractors are not so lucky. Indeed, Congress holds tight rein on the purse strings through laws imposing criminal liability on Executive agencies that fail to honor Congressional restrictions on amount, timing, and purpose of appropriated funds.⁴⁴ As one court noted, “[t]o make a contract obligating funds not yet appropriated is normally illegal, even criminal.”⁴⁵

What do these restrictions mean for Government contractors? Sometimes, contract awards, modifications, and option exercises are delayed until appropriated funds finally trickle down from Congress to the various Executive agencies. In other cases, agencies seek to dodge liability for payment by claiming a lack of funding.⁴⁶ Given that many Government contract clauses make the agency’s liability contingent “upon the availability of funds,” contractors who perform work or incur liabilities before such funds are available may find themselves empty-handed if Congress subsequently fails to appropriate the necessary funds.

Accounting and cost risks

For the typical Government contractor, a financial straitjacket of accounting rules and cost principles await. While some biotechnology companies and products may qualify for the limited exemptions, the risks and complexity are still daunting.

Cost Accounting Principles. For biotechnology research and development contracts, the cost principles would generally apply.⁴⁷ To oversimplify, the cost principles generally prohibit contractors from charging the Government for anything that is fun,

fattening, or illegal—e.g., entertainment, fines and penalties, or alcoholic beverages.⁴⁸ Many other cost principles allow costs to be charged only under limited conditions—e.g., advertising costs, consultant services, and travel costs.⁴⁹ If a contractor charges unallowable costs to a contract, a horde of Government auditors at the doorstep can be expected, all of whom are ready to disallow unallowable costs, doubtful costs, or simply costs unsupported by readily available accounting records.⁵⁰ For clear or repeated violations, a contractor may find itself on the wrong end of an action for administrative penalties⁵¹ or fraudulent claims.

Cost Accounting Standards. The Cost Accounting Standards (sometimes called CAS) establish a complex and relatively inflexible framework for accounting for costs relating to Government contracts.⁵² Blessedly, many exemptions exist, such as those for small businesses, fixed-price competitive contracts, and foreign contracts. However, biotechnology companies with the good fortune to receive large contracts (one or more of which exceed \$50 million) may then have the misfortune of torturing their accounting systems to comply with the Cost Accounting Standards. Once covered by the Cost Accounting Standards, a contractor must wrestle with Government administrative contracting officers over any accounting change, potentially resulting in Government recoupment of any cost impact of any such change that would favor the contractor.

Product and quality risks

Contracts for goods such as vaccines and medical devices often include detailed specifications and

⁴⁴ These laws are often referred to as the Anti-Deficiency Act. See 31 U.S.C. §§ 1341(a)(1)(A), 1301(a), 1502(a) and 1342.

⁴⁵ *Applied Devices Corp. v. United States*, 219 Ct. Cl. 109, 113 (1979).

⁴⁶ *United Technologies Corp., Pratt & Whitney Group*, ASBCA Nos. 46880, 46881, 97-1 BCA ¶ 28,828 at 143,797.

⁴⁷ FAR § 31.103(a).

⁴⁸ FAR §§ 31-205-14 (entertainment), 31-205-15 (fines, penalties, and mischarging costs), and 31.205-51 (alcoholic beverages).

⁴⁹ FAR §§ 31.205-1 (public relations and advertising costs), 31-205-33 (professional and consultant services), and 31.205-46 (travel costs).

⁵⁰ See FAR § 31.201.2(d) (cost disallowance of unsupported costs); FAR § 52.215-2(b) (audit rights and record-keeping requirements).

⁵¹ FAR §§ 42.703-2(a) and 42.709-1(a).

⁵² 48 CFR Chapter 99.

testing requirements. For such contracts, the company must generally maintain strict compliance with the specified requirements:

The Government is entitled to insist on strict compliance, and has no obligation to accept substitutes, even if the substitutes are equivalent or superior to that which is specified.⁵³

Increasingly, disputes over compliance with specification and testing requirements have shifted from contractual issues to allegations of fraud and false statements.⁵⁴ For these reasons, good manufacturing and quality controls are not only smart business, but also a key defense to false claims allegations.

Third-party liability

Imagine the following scenario: a biohazard detection device fails for unknown reasons, resulting in deaths of the entire first-response team secondary to an unidentified and untreated infection from a bioterrorism attack. Will the manufacturer survive the storm of resulting third-party liability suits that may follow? As a general rule, the Government does not—and cannot—indemnify its contractors against the hazards of third-party tort actions for defects in products sold to the Government.⁵⁵

In the Homeland Security Act of 2002, Congress has sought to address this risk in a subsection of the statute entitled the Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (the SAFETY Act). Under this provision, the Secretary of Homeland Security may designate “anti-terrorism technologies that qualify for protection under the system of risk management” for third-party liability suits and other similar risks.⁵⁶ However, such protection from tort liability comes with many strings attached, such as: (1) the seller must conduct “safety and hazard analyses” and submit information and a request for approval to get on the list; (2) the protection will not apply if the seller “acted fraudulently or with willful misconduct” to obtain such protection; (3) the Secretary must designate the product for the list; and (4) the seller must obtain a reasonable amount liability insurance for “compensable third-party claims.”⁵⁷ Until the regulations are issued and the Homeland Security Department develops a track record dealing with this new authority, the scope of protection from third-party liability suits remains uncertain for Government contractors.

Contract changes

In all of its contracts, the Government retains the rather unusual right to make unilateral changes.⁵⁸ If the contractor refuses, the Government may find the contractor in default and terminate the contract.⁵⁹ Of course, the contractor has a right to be paid for the cost of the change. However, getting paid is often a different matter, as the parties wrangle over the cost impact of the change while the work is ongoing. As a result, the contractor may end up financing the cost of the changed work, while the parties negotiate—or litigate—the real cost of the change. If the parties fail to agree on the cost and scope of the change, the contractor may litigate its rights before either a specialized board of administrative judges or the Court of Federal Claims.⁶⁰ When asserting claims for additional costs of performing the contract, a Government contractor—like a commercial contractor—bears the usual costs and risks of litigating and winning its dispute over the changed work. Unlike a commercial dispute, a claim under a Government contract entails the additional risk that the Government will seek forfeiture of the claim, treble damages, and penalties by asserting that the contractor’s claim is false.⁶¹

PROTECTING CONTRACT RIGHTS

As if getting and performing the contract is not hard enough, contractors must be careful to assert and protect their contract rights both during the course of the contract and after its conclusion. Examples of risks to such rights arise in the following areas: (1) intellectual property; (2) contract termination; and (3) debarment (blacklisting).

⁵³ *Carothers Constr. Co.*, ASBCA No. 41268, 93-2 BCA ¶ 25,628.

⁵⁴ *United States ex rel. Compton v. Midwest Specialties, Inc.*, 142 F.3d 296, 299 (6th Cir. 1998); *BMV-Combat Systems v. United States*, 44 Fed. Cl. 141, 148-50 (1998).

⁵⁵ *Hercules, Inc., v. United States*, 116 S. Ct. 981, 987 (1996); *California-Pacific Utilities Co. v. United States*, 194 Ct. Cl. 703, 715 (1971).

⁵⁶ Homeland Security Act of 2002, Pub. L. No. 107-296, § 862(b), 116 Stat. 2135 (Nov. 25, 2002).

⁵⁷ *Id.*, §§ 863-64.

⁵⁸ FAR § 43.103(b).

⁵⁹ FAR § 33.213.

⁶⁰ FAR § 33.211(a).

⁶¹ *United States v. White*, 765 F.2d 1469 (11th Cir. 1985).

Intellectual property rights

With its mammoth buying power, the Government has long used its leverage to gain at least a share—if not the entire package—of intellectual property rights in products sold to the Government. Indeed, Congress has been forced on more than one occasion to step in with statutory protection of contractor's rights in intellectual property, such as technical data rights.

Patent Rights. Of interest to small biotechnology firms (generally a firm with fewer than 500 employees), the Bayh-Dole Act usually allows contractors to retain patent title to “any invention of the contractor (1) conceived or (2) first actually reduced to practice in the performance of work under a funding agreement.”⁶² The Government obtains a “nonexclusive, nontransferrable, irrevocable, paid-up license” to use the invention for Government purposes,⁶³ leaving the contractor essentially with exclusive rights to the invention for commercial purposes. However, the contractor can lose these exclusive commercial rights in several ways, including failure to commercialize the invention within a reasonable period of time.⁶⁴

Trade Secrets. Congress has made it a crime for Executive agencies to disclose a contractor's trade secrets.⁶⁵ Nonetheless, such disclosures have happened from time to time, forcing contractors to seek damages or injunctive relief to protect their rights.⁶⁶

Data Rights. When the Government buys a product, it often seeks delivery of the technical data (e.g., drawing, blueprints, or descriptions) for that product. Years of agency tinkering, industry opposition, and Congressional intervention have produced a dense, complicated regulatory scheme defining the parties' rights in such technical data delivered under a contract.⁶⁷ However, the regulations do carve out some relatively safe harbors that accord contractors a high level of protection, giving the Government only “limited rights” in the data. For example, commercial items carry a presumption that any related data were developed at private expense, thus generally restricting the Government to limited rights in the data.⁶⁸ Such rights can be lost in a blink if the contractor fails to take steps to protect these rights, such as by including specific restrictive notices on any data delivered to the Government.⁶⁹

Contract termination

With the leverage of its enormous buying power, the Government retains a unique contractual right

for unilateral termination of a contract regardless of whether the contractor is at fault or not.

Default Termination. Since the Civil War, the Government has maintained a contractual right to terminate a contract for default where some contractor fault exists, such as late or non-compliant performance.⁷⁰ When the Government terminates a contract for default, it does not pay for unaccepted work, demands return of progress payments, and seeks recovery of any additional costs resulting from buying the product or services from another contractor.⁷¹ A default termination represents a “drastic sanction” by the Government.⁷² As a result, the courts closely scrutinize the Government's actions in such cases and afford a number of procedural and substantive protections to contractors in defending against such terminations.

Termination for Convenience. One of the most extraordinary rights of the Government is to terminate contracts unilaterally without any fault of the contractor.⁷³ In a termination for convenience, a contractor recovers costs and profit for any completed work, as well as certain costs for winding down the contract and settling the termination.⁷⁴ However, a Government contractor cannot recover anticipatory profits or consequential damages as a result of a termination for convenience.⁷⁵ The regulations contain detailed clauses and procedures governing these unique terminations.⁷⁶

Debarment and suspension

In no other business in the world can a single buyer blacklist a seller from a \$230 billion market.

⁶² 35 U.S.C. § 202(c)(1).

⁶³ 35 U.S.C. § 202(c)(4).

⁶⁴ 35 U.S.C. § 203(1).

⁶⁵ 18 U.S.C. § 1905.

⁶⁶ See *Ruckelshaus v. Monsanto*, 467 U.S. 986 (1984); *Megapulse, Inc. v. Lewis*, 672 F.2d 959 (D.C. Cir. 1982).

⁶⁷ FAR Subpart 27.4.

⁶⁸ FAR § 12.211.

⁶⁹ See, e.g., *Stanley Aviation Corp. v. United States*, 196 U.S.P.Q. 612, 620 (D. Colo. 1977); *Bell Helicopter Textron*, 85-3 BCA ¶ 18,415 at 92,432.

⁷⁰ FAR Subpart 49.4; FAR §§ 52.249-8, 52.249-9, 52.249-10.

⁷¹ FAR § 49.402-2.

⁷² See, e.g., *Lisbon Contractors, Inc. v. United States*, 828 F.2d 759 (Fed. Cir. 1987).

⁷³ FAR Subparts 49.2 and 49.3.

⁷⁴ FAR §§ 49.201, 49.206-2, and 31.205-42(b).

⁷⁵ FAR § 49.202(a).

⁷⁶ FAR Subparts 49.2 and 49.3; FAR §§ 52.249-1, 52.249-2, and 52.249-6.

The Government has the power to debar or suspend a contractor from receiving contracts for a period of time where the contractor has committed a fraud, offenses “indicating a lack of business integrity,” serious violations of contract terms, and other listed bad acts.⁷⁷ Due to the severe consequences of debarment and suspension upon contractors, the courts and regulations establish substantial procedural safeguards to protect contractors’ Constitutional due process rights against arbitrary or abusive Government actions.⁷⁸

CONCLUSION

For biotechnology companies, the Government is an attractive market, not only because it will be buying billions of dollars of biotechnology products and

services each year, but also because the Government has a long history of funding and developing cutting-edge technology, such as the Internet. However, the Government is a buyer like no other in the world, with unmatched buying power, highly specialized rules, and unique risks and costs not encountered in the commercial marketplace. For this reason, Government biotechnology contracts present both unique opportunities and particular risks. Biotechnology companies not already seasoned in dealing with this gargantuan customer must keep in mind a fundamental rule—seller beware—as they navigate the labyrinth of rules and procedures levied on Government contractors.

⁷⁷ FAR §§ 9.406-2 and 9.407-2.

⁷⁸ See, e.g., *Gonzalez v. Freeman*, 334 F.2d 570 (D.C. Cir. 1964).