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Takings Issues in the Approval of Generic Biologics

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I. INTRODUCTION

In order to streamline its pharmaceutical approval process, the Food and Drug Administration (FDA) soon may elect to rely on proprietary data supplied by branded companies for their original versions of approved biologics (or on the conclusions previously drawn from that data by FDA) in connection with its consideration of subsequent applications. Some brand-name industry sources have argued that such a practice might run afoul of the U.S. Constitution.[1] For a variety of reasons, however, the proposed regulatory change would not constitute an unconstitutional taking of property in violation of the Fifth Amendment. The contrary view would call into question the constitutionality of a number of well-established federal regulatory schemes, including the process for approving generic pharmaceuticals under the Hatch-Waxman Act.[2]

Recent proposals have devised a process for approving "generic" versions of drugs derived from living organisms (biologics). Assuming that FDA's use and treatment of such data is comparable to the agency's use of proprietary data under the Hatch-Waxman Act, there would be no violation of the Takings Clause. Any other conclusion would lead one to conclude that the Hatch-Waxman Act itself and FDA's application of that Act would violate the Constitution as well.[3]

II. BACKGROUND—THE HATCH-WAXMAN ACT

Any proposal for approving generic biologics presumably would be modeled, at least to some degree, on the approval of generic pharmaceutical products under the Hatch-Waxman Act. Because of this, it is worth reviewing that regulatory scheme at the outset.

Under section 505(b)(1) the Federal Food, Drug, and Cosmetic Act (FDCA), a pharmaceutical company that seeks to manufacture a new drug must file a new drug application (NDA) with FDA that includes information about the drug's safety and effectiveness.[4] The NDA also must include the number of any patent claiming the drug or a

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[1] *See GPhA Argues Biogenerics Approval Would Not Violate the Takings Clause*, FDA WK., Oct. 29, 2004, § 44 ("One of the key arguments against biogenerics is that such an approval system would violate the Takings Clause.").

[2] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in relevant part at 35 U.S.C. § 271 (2004)).

[3] Note that actions taken by local, state, or federal governments do not "violate" the Constitution in the same manner that they might violate other parts of the Constitution. A strict violation of the Fifth Amendment obtains only where the state offers inadequate or unjust compensation in exchange for its taking of private property. *See, e.g.*, Florida Prepaid Postsecondary Educ. Expense Bd. v. College Savings Bank, 527 U.S. 627 (1999).

> [A] State's infringement of a patent, though interfering with a patent owner's right to exclude others, does not by itself violate the Constitution. Instead, only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent could a deprivation of property without due process result.

Id. at 643.

[4] 21 U.S.C. § 355(b)(1) (2004).

method of using the drug. If FDA approves the NDA, it publishes the drug and the patent information in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the *Orange Book*).[5]

The Hatch-Waxman Amendments to the FDCA created a streamlined process for FDA to review applications by drug manufacturers to produce generic versions of drugs previously approved by the NDA process. Under section 505(j) of the FDCA, a generic producer may rely in part on FDA's conclusion that the brand-name drug is safe and effective by showing bioequivalence with the NDA-approved drug.[6] The Hatch-Waxman Amendments were enacted in 1984. Since then, no case has arisen in which any party has directly challenged FDA's reliance on its prior conclusions of safety and efficacy in connection with the abbreviated new drug applications (ANDAs) of generic companies.

It seems quite probable that generic "biologics"—meaning drugs that are produced by biological systems and organisms—would follow a similar FDA approval process. Historically, many biologics, generic and otherwise, have been approved under section 351 of the Public Health Services Act (PHSA).[7] As part of the PHSA process, a brand-name drug producer files safety and effectiveness data to support its application for a license to market a biologic drug. FDA regulations specify the nature of the data required.[8] The PHSA also contains a provision that makes clear that it does not affect FDA's jurisdiction under the FDCA.[9] Thus, FDA also may approve biologic products under the FDCA, as it has done with insulin and human growth hormone.

The PHSA does not make express provision for approving generic biologics similar to the ANDA approval process under the Hatch-Waxman Amendments to the FDCA. Presumably, because of the absence of this provision, FDA has expressed doubts concerning its authority to devise a generic approval process by regulation.[10] As a result, Congress is considering enacting legislation to provide a pathway for the approval of generic biologics.

Opponents of generic biologics argue that some paths to FDA approval would take private property without just compensation, as prohibited by the Takings Clause of the Fifth Amendment.[11] Specifically, they argue that any proposal allowing the generic applicant to draw upon data submitted by previous applicants, or to rely on information within the knowledge and experience of the agency that had been generated by previous applicants, would allow the "use" of property for a public purpose without just compensation. Because previously submitted data might, in some forms, constitute trade secrets—a form of intellectual property—opponents contend that any disclosure

[5] *Available at* http://www.fda.gov/cder/ob/docs/preface/ectablec.htm (24th ed.) (last visited May 9, 2005).

[6] 21 U.S.C. § 355(j)(2)(A).

[7] Ch. 288, 37 Stat. 309 (1912) (codified in relevant part at 42 U.S.C. § 262 (2004)).

[8] 21 C.F.R. § 601.2 (2004).

[9] 42 U.S.C § 262(j).

[10] FDA's concerns in this regard seem to be unwarranted. The PHSA grants to the Secretary of the Department of Health and Human Services (DHHS) the authority to approve licenses for the production of biologics if the product is "safe, pure, and potent" and is manufactured in a facility with processes by which the product continues to be safe, pure, and potent. 42 U.S.C. § 262(a)(2)(C). It gives the DHHS Secretary the power to "establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses." *Id.* § 262(a)(2)(A). The Secretary already has used this rulemaking authority to establish procedures for the approval of biologics. *See* 21 C.F.R. § 601.2. Under this authority, there seems to be no statutory obstacle to the Secretary's potential decision to allow the agency to rely on previously submitted safety and effectiveness studies in considering later generic applications or on information already within the agency's knowledge and experience.

[11] U.S. CONST. amend. V ("[N]or shall private property be taken for public use without just compensation.").

or use of the information by the agency would constitute a taking for which "just compensation" is required by the Constitution. The remainder of this article addresses this argument, and concludes that no taking would occur as a result of the proposals to allow approval of generic biologics.

III. THE LAW OF TAKINGS

Brand companies suggest that a process for approving generic biologics permitting reliance on proprietary data in approving subsequent applications could potentially constitute an unconstitutional taking of private property under the Fifth Amendment.[12] They assert that proprietary data and other information submitted in support of any application for agency approval constitute trade secrets, which, coupled with FDA's long-standing practice of nondisclosure, creates a reasonable investment-backed expectation that agency use of the data in approving a generic version would constitute a taking. A review of Takings Clause case law, with particular attention to its application to regulated industries, demonstrates that FDA's proposed change in approving biologics will not, in fact, constitute a taking.

The Takings Clause applies to governmental seizure of property, such as the exercise of the power of eminent domain. Physical occupation or seizure of land by the government, for example, triggers the obligation that the government pay just compensation.[13] The Takings Clause also applies in some instances where government regulation causes a sufficiently large diminution in the value of an individual's property, even when that regulation does not result in actual physical occupation of the property.[14] The law of takings as applied to dimunition of value in property caused by governmental regulations is significantly different than the law relating to physical property:

> Government could hardly go on if to some extent values incident to property could not be diminished without paying for every such change in the general law. As long recognized, some values are enjoyed under an implied limitation and must yield to the police power.[15]

In *Mahon*, the Court observed that when regulations imposed by the state entirely eliminate the value of the property at hand, a taking has occurred and just compensation must be provided. As Justice Holmes explained, "[t]he general rule at least is that while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking."[16] Since this decision, the Court has gone to great lengths to establish guidelines for determining when governmental regulation of property has gone "too far" and thus amounts to a taking.

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[12] *See Senate Committee Considers Biologics*, WORLD GENERICS MKT., July 12, 2004 (noting that one representative from Amgen argued before the Senate Judiciary Committee that the proposed change would violate the Fifth Amendment if not accompanied by just compensation).

[13] *See, e.g.*, Hawaii Housing Authority v. Midkiff, 467 U.S. 229, 231-32 (1984); Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 441 (1982). Outside the scope of this article is a third type of takings jurisprudence, which precludes, in all instances, government seizures of private property for nonpublic uses. *See Midkiff*, 467 U.S. at 229 (finding that state law guaranteeing native Hawaiians exclusive opportunities for apartment bidding constituted a "public use," and was therefore not *per se* invalid state action); *but see* County of Wayne v. Hathcock, 471 Mich. 445, 684 N.W.2d 765 (2004) (finding that local government's condemnation of private land for technology park was *per se* invalid for lack of public use).

[14] Pennsylvania Coal Co. v. Mahon, 260 U.S. 393, 415 (1922) ("We are in danger of forgetting that a strong public desire to improve the public condition is not enough to warrant achieving the desire by a shorter cut than the constitutional way of paying for the change.").

[15] *Id.* at 413.

[16] *Id.* at 415.

Notably, government regulations typically do not implicate the same Fifth Amendment jurisprudence as occupations or appropriations of private property. Courts evaluate physical occupation cases, involving the outright taking of title or appropriation of tangible property for public use, under a *per se* rule. Such regulations that deprive the owner of the property of the fundamental right to "exclude others" violate the Fifth Amendment.[17] On the other hand, courts evaluate regulations that merely place burdens on an owner's exercise of property rights with significantly less scrutiny. As the Supreme Court observed in 2003, "[o]ur regulatory takings jurisprudence, in contrast, is of more recent vintage and is characterized by essentially *ad hoc*, factual inquiries, designed to allow careful examination and weighing of all the relevant circumstances."[18]

Of course, even if a regulation of property leaves the owner with his or her "right to exclude," courts will still characterize the regulation as a *per se* taking if the regulation effectively destroys "*all* economically beneficial uses" of the property, so long as the regulated activity is not a nuisance-like activity prohibited or constrained at common law.[19] Yet, courts have recognized that such value-diminishing regulations are very rare occurrences. Indeed, even where government regulation of property results in a high (but not complete) diminution of value, the courts will not apply the *per se* rule that a taking has occurred. As the Court stated just three years ago:

> The categorical rule that we applied in *Lucas* states that compensation is required when a regulation deprives an owner of *all* economically beneficial uses of his land. Under that rule, a statute that wholly eliminated the value of Lucas' fee simple title clearly qualified as a taking. But our holding was limited to the extraordinary circumstance when *no* productive or economically beneficial use of land is permitted. The emphasis on the word "no" in the text of the opinion was, in effect, reiterated in a footnote explaining that the categorical rule would not apply if the diminution in value were 95% instead of 100%. Anything less than a complete elimination of value, or a total loss, the court acknowledged, would require the kind of analysis applied in *Penn Central*.[20]

Accordingly, unless government regulation completely deprives property of its entire value, courts will not find a *per se* taking to have occurred.

Even where property owners are unable to demonstrate either an outright appropriation or the absolute loss of economic value of their property, they may yet have a viable takings claim. In the vast majority of cases, where no *per se* taking has occurred, the courts balance the competing public and private interests at issue in evaluating governmental confiscations of property. Takings analysis in this context becomes a function of a) the character of the governmental action; b) its economic impact; and c) its interference with reasonable, investment-backed expectations.[21] The Supreme Court, in fact, has applied this analysis to the context of regulatory decisions approving products and

[17] *See* Kaiser Aetna v. United States, 444 U.S. 164, 179-80 (1979); *Loretto*, 458 U.S. at 434-35; Nollan v. California Coastal Comm., 483 U.S. 825 (1987).

[18] Brown v. Legal Found. of Wash., 538 U.S. 216, 233 (2003) (internal quotations and citations omitted).

[19] Lucas v. South Carolina Coastal Council, 505 U.S. 1003, 1019 (1992) (emphasis in original).

[20] Tahoe-Sierra Preservation Council, Inc. v. Tahoe Reg'l Planning Agency, 535 U.S. 302, 330 (2002) (emphasis in original) (internal quotations and citations omitted) (citing Penn Central Transp. Co. v. City of New York, 438 U.S. 104 (1978)).

[21] *Penn Central*, 438 U.S. at 124; Pruneyard Shopping Ctr. v. Robino, 447 U.S. 74, 83 (1980).

the value of information provided to an agency by a private party. The foundational case is *Ruckelshaus v. Monsanto Co.*[22]

In *Monsanto*, the Court addressed a takings claim against the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[23] under which the Environmental Protection Agency (EPA) approves pesticides. As first enacted, FIFRA required an applicant to submit test data supporting the claims on the label of a pesticide, and prohibited disclosure of "any information relative to formulas of products," but did not address the disclosure of health and safety data.[24] In 1972, Congress amended FIFRA to create a comprehensive regulatory scheme for pesticides that governed their use as well as their sale and labeling, and required EPA to find that a pesticide would not cause "unreasonable adverse effects on the environment" before approving it for sale.[25]

The 1972 FIFRA amendments contained several changes regarding the use and disclosure of application data. First, Congress allowed the applicant to designate portions of the data as "trade secrets or commercial or financial information," and prohibited EPA from publicly disclosing information containing such information.[26] Second, Congress permitted EPA to consider data submitted by one applicant to support a different application for a similar chemical. Significantly, in order to take advantage of this provision, the second applicant had to offer to compensate the first applicant who had submitted the original data.[27] Despite this "mandatory data-licensing scheme," Congress prohibited EPA from considering any trade secret, commercial, or financial information to support a second application without the consent of the original applicant.[28] Courts interpreted this information to include health, safety, and environmental data consistent with the definition of trade secrets in the *Restatement of Torts*.[29]

Congress again amended FIFRA in 1978. Under the 1978 amendments, applicants received a ten-year period of exclusive use for data on new active ingredients in pesticides filed after September 1978.[30] For applications submitted before September 1978 but after December 1969, EPA could consider data in support of a second application at least fifteen years after the original submission. Like the 1972 scheme, the second applicant was required to offer compensation to the first applicant.[31] The 1978 amendments also permitted qualified persons to request disclosure of all health, safety, and environmental information, except for "manufacturing or quality control processes" and other details, unless EPA's administrator decided that disclosure was necessary to protect against unreasonable risk of injury to health or the environment.[32] Criminal penalties were provided for wrongful disclosure by the government of confidential or trade secret data.

In response to a takings challenge by a company that had submitted proprietary data, the Court considered the various amendments and their effective dates, finding that whether compensation for takings might be required depended on the nature of the

[22] 467 U.S. 986 (1984) (Justice Blackmun wrote the opinion of the Court for a seven-Justice majority; Justice O'Connor concurred in part and dissented in part; Justice White took no part in the decision).

[23] Pub. L. No. 100-532, 102 Stat. 2654 (1988) (codified at 7 U.S.C. et seq. (2004)).

[24] *Monsanto*, 467 U.S. at 991.

[25] *Id.* at 992 (citing 86 Stat. 980-81).

[26] *Id.* (citing 86 Stat. 989).

[27] *Id.* If negotiations between the first and second applicant failed to reach an agreement on compensation, then EPA was directed to determine an amount, subject to judicial review. *Id.* at 992.

[28] *Id.* at 992-93.

[29] *Id.* at 993.

[30] *Id.* at 994.

[31] *Id.* If the parties could not agree on an amount, then they could seek binding arbitration. If the first applicant refused to negotiate or participate in arbitration, then it lost its right to compensation. *Id.*

[32] *Id.* at 996.

disclosure regime established by Congress. First, the Court agreed that the health, safety, and environmental data could be considered a trade secret under state law. Because trade secrets shared many of the characteristics of other intangible forms of property (e.g., they could be assigned or be the *res* of a trust, and that state law had found trade secrets to be property),[33] the Court found that trade secrets were protected by the Takings Clause.[34] The Court further found that, with respect to trade secrets, a) the property right is defined by an owner's ability to protect the information against disclosure by third parties, and b) information generally known in an industry or through public knowledge could not constitute a trade secret.[35] Significantly, the Court also found that any property right could be extinguished if an owner discloses the trade secret to another who has no obligation to maintain its confidentiality.[36]

Second, the Court applied the *Penn Central* three-pronged test to claims of unauthorized disclosure of trade secret data. In applying this test to FIFRA, the Court held that an applicant could not have any reasonable investment-backed expectation with regard to data submitted after the 1978 amendments came into effect.[37] The Court found that Congress' change in the rules to allow EPA to consider the data after a ten-year period; its requirement of an offer of compensation from subsequent applicants; and the provision permitting the disclosure of health, safety, and environmental information to public requesters, all put the applicant on notice that it could not expect its data to remain confidential.[38] In other words, the statute, after the 1978 amendments, could not give rise to any investment-backed expectations cognizable under the Takings Clause. As the Court observed:

> If, despite the data-consideration and data-disclosure provisions in the statute, [the applicant] chose to submit the requisite data in order to receive a registration, it can hardly argue that its reasonable investment-backed expectations are disturbed when EPA acts to use or disclose the data in a manner that was authorized by law at the time of the submission.[39]

The result of this holding with regard to data submitted for government approval is clear:

> [A]s long as [the applicant] is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking.[40]

Third, the Court examined whether the pre-1972 FIFRA regime created sufficient conditions to give rise to investment-backed expectations concerning the confidential-

[33] Other forms of intellectual property had long been held to bestow standard property rights upon their owners. *See, e.g.*, Int'l News Serv. v. Assoc. Press, 248 U.S. 215 (1918) (finding that a newspaper's knowledge of world events did invest the newspaper with a concrete property interest).

[34] *Monsanto*, 467 U.S. at 1002-04.

[35] *Id.* at 1002.

[36] *Id.*

[37] *Monsanto*, 467 U.S. at 1006.

[38] *Id.*

[39] *Id.* at 1006-07.

[40] *Id.* at 1007. It also should be noted that the post-1978 regulatory scheme did not destroy the value of the trade secret to the original submitter. EPA could itself consider the confidential data in evaluating a subsequent application, but only if the subsequent applicant paid compensation and then only after a 10-year period of exclusivity.

ity of submitted data. Prior to the 1972 amendments, the Court observed, the statute made no promises concerning the confidentiality of data. Although the Trade Secrets Act[41] creates criminal penalties for government employees who engage in unauthorized disclosure of trade secrets, the Court found that these provisions did not guarantee that the government would refrain from using an applicant's data itself when approving successive applications.[42] In the absence of any explicit and specific guarantee of confidentiality, the Court found that an applicant has "no reasonable investment-backed expectation that its information would remain inviolate in the hands of the EPA."[43] In fact, in regulated industries, the Court observed that applicants could expect that such information might be disclosed:

> In an industry that has long been the focus of great public concern and significant government regulation, the possibility was substantial that the Federal Government, which had thus far taken no position on disclosure of health, safety, and environmental data concerning pesticides, upon focusing on the issue, would find disclosure to be in the public interest.[44]

Significantly, the Court reached this conclusion over the dissent of Justice O'Connor, who had argued that statutory silence and no customary agency practice militated in favor of finding a taking. Statutory silence in a heavily-regulated industry, the Court found, has the opposite effect—it places applicants on notice that they cannot form reasonable investment-backed expectations that submitted data will not be used by the agency in the future.

Fourth, the Court found that the FIFRA regime in existence from 1972-1978 may have provided the guarantees necessary to prohibit the government from using an applicant's data when approving a successive application. Thus, any data submitted during that timeframe could not be used by EPA without just compensation. In deciding that the 1972-1978 statutory scheme created a reasonable investment-backed expectation, the Court relied upon the fact that the statutory text during that period: a) permitted the applicant to protect data by designating it a trade secret; b) barred EPA from using trade secret data submitted during this period in considering another application; and c) allowed non-trade secret data to be considered in connection with another application if it required reasonable compensation to the first applicant.[45] With these express statutory provisions, the Court concluded that "the Federal Government had explicitly guaranteed to [applicants] an extensive measure of confidentiality and exclusive use. This explicit governmental guarantee formed the basis of a reasonable investment-backed expectation."[46] Disclosure of trade secret data "to others" destroys the property interest of the owner, even if the data continues to be useful to the applicant.[47]

IV. THE AGENCY CAN APPROVE GENERIC BIOLOGICS WITHOUT EFFECTING AN UNCONSTITUTIONAL TAKING

Seemingly, then, a proposal to permit the approval of generic biologics similar to the FDCA would not raise a takings issue.

Initially, it is worth considering in greater detail just what property interest would be threatened by a scheme similar to the FDCA. The companies that submit confidential

[41] Ch. 645, 62 Stat. 791 (June 25, 1948) (codified in relevant part at 18 U.S.C. § 1905 (2004)).
[42] *Monsanto*, 467 U.S. at 1008-09.
[43] *Id.* at 1008.
[44] *Id.* at 1008-09.
[45] *Id.* at 1010-11.
[46] *Id.* at 1011.
[47] *Id.*

information in support of their applications would argue that the regulatory scheme threatens their trade secret property interest in the information. In the FDCA context, however, what FDA relies on in considering an ANDA is not the proprietary data itself, but FDA's own prior determination that the data established that the *Orange Book*-listed drug was safe and effective. As long as the ANDA applicant's drug is bioequivalent—something the ANDA applicant itself must establish—the statute permits FDA to conclude, in effect, that it does not need to reconsider the safety and efficacy question *de novo*. The agency used the proprietary data itself only in considering the original NDA. With respect to ANDAs, it merely uses the public, non-trade secret *fact* that it concluded that the innovator drug was safe and effective. It is very difficult to view this as a use of the innovator's trade secrets, much less a use that gives rise to a takings issue.[48]

Moreover, even if the agency's reliance on its prior conclusions for subsequent applications is—in some pertinent sense—a use of the innovator's trade secrets, no reasonable investment-backed expectations for brand-name companies could exist under the current FDCA statutory regime or, in reality, under any comparable regime for approving generic biologics. In *Monsanto*, as the Supreme Court observed, during the 1972-1978 statutory scheme, Congress specifically amended the relevant statute to a) allow an applicant to designate information as a trade secret, b) prohibit the agency from using that information, and c) require compensation for the use of non-trade secret information. The FDCA does not contain any such provisions. While Congress certainly could choose to provide comparable guarantees to the proprietors of trade secret information submitted to FDA, as Congress did for a brief period under FIFRA, there is no constitutional obligation to do so if the trade secrets are not destroyed by the agency's disclosing them publicly.

The current FDCA scheme is analogous to the pre-1972 FIFRA examined in *Monsanto*, where the Court found that an applicant has "no reasonable, investment-backed expectation that its information would remain inviolate in the hands of EPA."[49] Here, as there, the relevant statutes are silent with regard to the use of application data for the approval of subsequent applications. And where Congress has established a discretionary system that temporarily benefits a class of manufacturers and that permits FDA to interpret it within its discretion to disadvantage the same class, no investment-backed expectation is *reasonable*.

Opponents of generic biologics might argue that one provision of the FDCA does provide a guarantee sufficiently reliable to give rise to a reasonable investment-backed expectation, as defined by *Monsanto*. Title 21 U.S.C. section 331(j) prohibits:

[48] In addition, some companies have argued that in the course of approving a company's application, the agency will acquire knowledge of proprietary technology that the agency will inevitably "use" in considering subsequent applications for similar products; that such "use" constitutes a misappropriation of trade secrets; and that generic applicants should be required to make a showing identical to innovators to avoid giving the generic applicants the unfair "benefit" of the tutorial that the innovator gave to the agency.

This argument is incorrect for several reasons. It is very doubtful that the general knowledge acquired in connection with the agency's consideration of innovator applications constitutes a trade secret or that the use of it constitutes the misappropriation of trade secrets. The common law of trade secrets recognizes that employees may use the general "know-how" they acquire in their jobs when they switch employers, even if the employee had been exposed to proprietary information. The employee may not use or disclose specific trade secrets, but the fact that the exposure to proprietary data may have made the employee a better engineer or chemist does not give the former employer the right to prevent the employee from working in his or her chosen field. Similar principles would apply to a regulatory agency. Moreover, even if there were a risk of misappropriation, a specific act of misappropriation does not necessarily amount to a taking. As long as the agency does not destroy the trade secrets, or (what amounts to the same thing in this context) dedicate them to the public-by-public disclosure, the brand company's property interest remains intact and there is no *per se* taking.

[49] *Monsanto*, 467 U.S. at 1008.

> [t]he using by any person to his own advantage, or revealing, other than to the Secretary or official or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of sections 404, 409, 412, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 708 or 721 concerning any method or process which is a trade secret is entitled to protection.[50]

This provision appears on its face to prohibit an individual from "using" information submitted to the agency, if it qualifies as a trade secret, to his or her "advantage." It also prohibits the revelation of this information except to other members of DHHS or the courts. There are several reasons, however, why 21 U.S.C. § 331(j) does not amount to a guarantee of confidentiality as described in *Monsanto*.

First, this provision is not a clear prohibition against the use of submitted data to approve subsequent applications. In *Monsanto*, for example, FIFRA explicitly prohibited the use of submitted data for such purposes. Here, by contrast, there is only a general prohibition on the use or revelation of trade secrets, and it expressly excludes intra-agency disclosures. Section 331(j) is akin, therefore, to the Trade Secrets Act, which generally bars the unauthorized disclosure of trade secrets, but which the *Monsanto* Court found did *not* serve as a guarantee against future intra-agency use of submitted data.

Second, on its face, section 331(j) does not prohibit the use of submitted data for official purposes, such as approving subsequent applications for the same biologic. Section 331(j) prohibits two types of conduct: 1) use of a trade secret by a government employee "to his own advantage," and 2) revelation of a trade secret outside DHHS. Use of the information to approve a biologic does not amount to the type of private gain that concerned Congress in the first part of the statute.

Similarly, section 331(j) permits the disclosure of the information within DHHS. If, in approving a generic drug company's application for a biologic, FDA publicly stated that it had relied on earlier submitted data, but did not disclose the trade secret data, it would not be in violation of the second part of the statute. The second part of the statute prohibits only public disclosure, but not use by DHHS of the information. In fact, in order to give every word of the statute meaning, section 331(j) should be read to permit DHHS' official use of trade secret data. Because the statute specifically prohibits only use of the information by a government employee "to his own advantage," it necessarily permits use of trade secret information by DHHS in its official functions so long as it does not publicly reveal that information.[51]

Third, section 331(j) stands alone. It is not accompanied by other statutory provisions that, together, would indicate that Congress intended to provide guarantees to applicants that their data would remain confidential. Unlike the statutory scheme in *Monsanto*, nothing in the FDCA indicates that Congress has drawn a careful line between the trade secret data that FDA may not rely on in evaluating subsequent applications and the non-trade secret data on which it may rely. In fact, the statute does not address the issue at all. Unlike the statute in *Monsanto*, here Congress has not created

[50] 21 U.S.C. § 331(j).

[51] Some have suggested that FDA's internal documents interpret "to his own advantage" as including a benefit to either the FDA employee or others. *See* Genentech Citizen Petition, Dkt. No. 2004P-0171/CP, at 12-13 (Apr. 8, 2004). Even under this line of reasoning, FDA's use of submitted data to approve a subsequent application is not such a benefit. The obvious sense of barring use to the "advantage" of others is that of barring private enrichment *at the expense of the public interest.* Plainly, use in furtherance of the approval of generic drugs or biologics serves the public interest in reducing healthcare expenditures. Further, these internal agency documents are not formal statutory interpretations, and can be altered at any time.

any compensation scheme by which the subsequent applicant is required to compensate the first applicant; has not included a mandatory procedure for negotiation or arbitration of the amount of compensation; nor has it guaranteed applicants that their data would not be used or disclosed for any other purpose.[52]

Fourth, reading section 331(j) to bar official use by FDA of previously submitted data would be absurd. Suppose that a pharmaceutical company submitted a seriously flawed application to produce a biologic. Suppose FDA knew that the application was flawed based upon data submitted in an earlier application for the same biologic. Under a broad reading of section 331(j), it would be illegal for FDA to take this earlier information into account. Nothing in the text of section 331(j) supports this result. If section 331(j) permits FDA to consider information already in its possession to reject a flawed application, it also should allow FDA to consider that same type of information to approve an application that meets the agency's safety and effectiveness standards.

All of this leads to the conclusion that a process for the approval of generic biologics under a process similar to that employed under the Hatch-Waxman Act (i.e., one that permits the agency to rely upon data previously submitted by an earlier applicant or upon the conclusions the agency previously reached with regard to that data) would not constitute a taking under the principles set forth in *Monsanto*. In the absence of express guarantees that such proprietary information will not be used—guarantees that Congress need not give and should not give if the goal is to encourage the development of generic biologics—an earlier applicant could not have the reasonable investment-backed expectations needed to give rise to a property interest cognizable under the Takings Clause.[53]

Opponents of generic biologics have argued that FDA, through its regulatory guidance, has created such expectations. Assuming *arguendo* that sufficient evidence exists to support such an argument, it is still improbable that FDA's use of prior brand data constitutes a taking.

Even if FDA had issued a guidance guaranteeing that innovator data would not be used when approving subsequent applications, such guidance would not create the reasonable investment-backed expectations that the Supreme Court requires. Such promises must be statutory in nature, and set forth in connection with the statute that authorizes the use of the information by the agency for more limited purposes. In *Monsanto*, for example, even though the Trade Secrets Act prohibited government officials from disclosing information, the Court found that FIFRA contained no express promise and thus did not create the type of reliance interest necessary to find a taking.[54] Thus, the Court stated that "[i]n an industry that has long been the focus of ... significant government regulation, the possibility was substantial that the Federal Government, ..., upon focusing on

[52] In its ANDA regulations, FDA has provided that an NDA applicant can include a "right of reference or use" for data owned by another. 21 C.F.R. § 314.50(g)(3). This is not a requirement that FDA itself must have the permission of the original applicant to consider submitted data, if it is already in the agency's possession.

[53] It also should be clear that any takings claim based on this theory—even if one existed—could apply only to data submitted before any FDA rule change. Once the reclassification of generic biologics occurs, pharmaceutical companies who continue to submit trade secrets to FDA will fully know that those trade secrets could be "used" to approve subsequent applications. *See Monsanto*, 467 U.S. at 1006. Companies who submit trade secrets to FDA while on notice of FDA's practices will not be able to claim that they maintained reasonable investment-backed expectations that their trade secrets would not be used in the manner described by FDA. *Id.* at 1005 ("A reasonable investment-backed expectation must be more than a unilateral expectation or an abstract need.") (citation omitted). Any question of a taking can involve only data submitted before any FDA rule change.

[54] *Monsanto*, 467 U.S. at 1008 ("[A]bsent an express promise, Monsanto had no reasonable, investment-backed expectation that its information would remain inviolate in the hands of EPA.").

the issue, would find disclosure to be in the public interest."[55] If an applicant participates in a heavily-regulated industry—and no one could doubt that pharmaceuticals are as much a regulated industry as pesticides[56]—they cannot reasonably expect that an agency will maintain its current regulations in effect forever.

V. CONCLUSION

If FDA decided to use the knowledge acquired by a pioneer company in furtherance of a subsequent approval of a generic biologic drug, the agency likely would encounter no significant takings issue. Although owners have very real property rights in their trade secrets, those rights would not preclude FDA from using knowledge that it has already obtained in an internal agency decisionmaking process. Moreover, even if some pioneer companies do possess reasonable investment-backed expectations, it must be acknowledged that the pharmaceutical industry is one of the most heavily regulated of any industry in modern commerce, and that government alterations in regulatory schemes come with the territory of doing business in the market. For these reasons, FDA's decisions in this area should be based purely on policy considerations, and should not be deterred by Fifth Amendment concerns.

[55] *Id.* at 1008-09.

[56] *See* John C. O'Quinn, *Protecting Private Intellectual Property From Government Intrusion: Revisiting SmithKline and the Case for Just Compensation*, 29 PEPP. L. REV. 435, 500 (2002) ("In a heavily regulated field (such as pharmaceuticals) the standard for finding reasonableness in investment-backed expectations is higher than in largely deregulated activities.").