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FDA Law:
The TriCor Litigation**

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I. INTRODUCTION

The purpose of this brief essay is to address the interconnections among three important areas of law: antitrust, patents, and FDA regulation. Each of these presents formidable difficulties in its own right. The integration of any two areas of law is always vexed. The interconnections among three different bodies of law of vital relevance to the pharmaceutical industry present a still more formidable challenge. The easiest approach starts with an outline of the antitrust, into which I shall first integrate the patent law, thereafter turning to the rules governing FDA approved drugs.

In order to focus the inquiry I will talk about the TriCor litigation in which Abbott Labs was sued on three fronts: by downstream retailers, generic competitors, and state attorneys general.¹ The three cases raise much the same substantive issues, even though each group has its own distinctive damage claim. The litigation has clear importance

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¹For the retailers' complaint, *see* *Walgreen Co. v. Abbott Labs*, (D.Del., 2005), *available at* <http://www.pharmalot.com/wp-content/uploads/2008/11/walgreen-v-abbott.pdf>.

because TriCor generates over a billion dollars in sales each year. The stakes are high. It is worth noting that the retailer piece of the litigation was recently settled for \$184 million.²

II. ANTITRUST LAW—NO ALL-PURPOSE TOOL

The first point is that we must be modest about the scope of the antitrust law. It does well in combating cartels, where there is a clear theory as to why these arrangements are harmful to social welfare. It works worst when it is invoked as a panacea for the world's ills. The intermediate case is where a firm is attacked under Section 2 of the Sherman Act for unilateral practices by a single firm.³ The key feature of these cases is that they do not normally involve cooperative behavior among multiple defendants, as do cases dealing with cartels or (in a different institutional setting) mergers.⁴ Sorting out section 2 cases is the central conceptual challenge of the modern antitrust system.

The TriCor litigation falls into this middle class. To see how the argument plays out, it is easiest to start with the allegations found in the complaint in the Direct Purchaser TriCor litigation, which gives good insight into the range of relevant issues. The usual elements of a monopolization claim under Section 2 require that someone

²Shirley Wang, *Abbott to Pay \$184 Million in Tricor Suits*, WALL STREET J., (November 21, 2008), available at: <http://online.wsj.com/article/SB122723435863546927.html>

³Section 2. Monopolization; penalty. Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$10,000,000 if a corporation, or, if any other person, \$350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

⁴Hence the title of the recent government study, DEPARTMENT OF JUSTICE, COMPETITION AND MONOPOLY: SINGLE FIRM CONDUCT UNDER SECTION 2 OF THE SHERMAN ACT, (September, 2008).

define the market taken over by the defendant, and then indicate the types of (improper) practices that have been used to acquire, maintain, or expand the monopoly in question.⁵

III. MARKET DEFINITION

Market definition issues are always hard to negotiate, but the difficulties are especially acute in dealing with pharmaceuticals where it is easy to make the leap from “exclusive rights under patents” to monopoly within a field. The recent Supreme Court decision in *Illinois Tool Works, Inc. v. Independent Ink, Inc.*,⁶ proves helpful in this connection because it holds that there is no presumption of market power from the existence of a valid patent over a given invention or process, and remanded the case for further determinations on the remaining issues of market definition and market power. Needless to say, without the patent presumption of market power, the plaintiffs face major difficulties in making a monopolization claim in a market in which “at least two other companies” supply products in the specialized niche of affixing bar codes to cartons.⁷ There is no difficulty in showing that the plaintiff has been hurt by the competition. But there is much difficulty in showing that the competitors’ interest lines up with the social interest in consumer welfare.

The situation with respect to market definition for pharmaceutical products is always more complex. For example, the simple observation that all drugs treating a single condition should be grouped in the same market runs into difficulties with cholesterol

⁵United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966), relying heavily on United States v. Aluminum Co. of America, 148 F.2d 416 (2d Cir. 1945). Note that Grinnell and Alcoa both had a weirdly narrow definition of the relevant market. But their influence still remains substantial on the general question of monopolization.

⁶547 U.S. 28 (2006).

⁷See *Indepen. Ink, Inc. v. Trident, Inc.* 210 Supp.2d 1155 (C.D.C. 2002).

because some individuals cannot switch across different classes of drugs, and others cannot switch to different drugs within the same class. There is a good deal of skepticism among many Chicago-type economists over the notion of a “submarket,” but the concept continues to hold some judicial appeal in light of the heterogeneity of product users. This heterogeneity should, in principle, allow for some price discrimination—at least if the product seller can find effective ways to sort its customers and to prevent resale at either the wholesale or retail level, which is hard to do. But that said, a key question in the TriCor litigation asks about the level of substitutability for TriCor with different drugs in the same class and with different products in different classes. More concretely, one of the allegations in the Walgreen Complaint is that there is perfect substitutability between the older TriCor capsule that was pulled from the market and the newer tablet that was put in its place.⁸ That claim is clearly critical to the case and it was denied by Abbott, which argued that each of the two basic drug reformulations had an independent efficiency purpose; the first to raise good cholesterol and the second to allow administration of the drug without food.⁹

On these factual disputes, I have nothing useful to say. But the salience of the point for legal purposes is clear. The greater the difference between the two formulations of the same drug, the easier it is to justify the shift in product on the kinds of efficiency grounds that undermine a Section 2 case. If the two products are not perfect substitutes

⁸See Walgreen Complaint ¶37: “Importantly, these tablets offered no benefit to consumers because they contained the same drug as the earlier-approved capsules and were therapeutically and bioequivalent to the capsules.”

⁹Shirley Wang, *Tricor Case May Illustrate Patent Limits*, WALL STREET BUS. (June 2, 2008): “It [Abbott] says the two switches brought improvements for patients. The first reformulation enabled the drug to raise patients’ good cholesterol and the second eliminated the requirement that it be taken with food, Abbott adds.”

for each other, litigation can no longer focus on a narrow market that consists of “the” drug. It must acknowledge that the differences matter. Once that is done, the overall market could be larger still, and include products made by third persons that bear an imperfect resemblance to both the drugs. Put otherwise, the greater the chemical and structural difference between the competing products, the broader the necessary market definition. That broad definition could pose a serious threat to the viability of any Section 2 case.

Matters can easily become more complicated. There are some situations in which a firm has power with respect to certain key activities, even if it does not have broad market power in all the areas in which it operates. One line of cases dealing with repairs and replacements of copier parts—the *Eastman Kodak* litigation¹⁰—stands for the proposition that a firm does not have to have market power in the primary market in order to engage in the exclusive dealing in the aftermarket that gives rise to a valid monopolization claim. The argument that prevailed before a sharply divided court was that if the plaintiff could identify those people who have to buy Kodak parts and services because they bought Kodak copiers, these purchasers constitute the proper “after” market, even if Kodak has no market power in the general copier market.

Kodak was very tricky and much mooted.¹¹ In my view, the narrow factual pattern that made *Kodak* a credible case for the plaintiff depended on its conduct after the original equipment sales. Kodak’s strategy was either to acquire or to make agreements with all the repair firms *after* it sold the original equipment to its customers. Those

¹⁰*Eastman Kodak v. Image Tech Services*, 504 U.S. 451 (1992).

¹¹*See*, Department of Justice Study, at 81, 120-125.

business deals critically changed the structure of the aftermarket, which was no longer as competitive as it had been at the time of the initial sales. The original service options that were available at the time of sale disappeared. Yet there was no notice to Kodak purchasers at the time of their initial purchases that they would be faced with an aftermarket monopoly position; a notice which, if given, should have flipped the case over into the category of *per se* legal.¹² Academic commentators are divided on whether this pattern of conduct should give rise to an antitrust or a contract suit, but the plaintiff did win a substantial antitrust verdict on remand.¹³ What is clear today is that, if there is an explicit understanding that the original package covers parts and labor, it is hard to win on Section 2, either on grounds of an illegal tie-in or refusal to deal, for want of market power in the primary market. So the sands can easily shift.

In the TriCor litigation, the argument is that there is a submarket defined by medical conditions so that Abbott has some captive customers who cannot take or use any products in the field other than TriCor. But the analysis requires precise knowledge of the size of this group, and how quickly they are identifiable. There is some fraction of these people who can use only one of these products, but these people are not known in advance, and they will receive protection because no company can afford to be indifferent to the risk that some other portion of their base will switch if prices are raised. Price discrimination is a feature in all patent markets where the patent holder holds a

¹²*See, e.g.,* Hack v. Yale College, 128 F. 3d 59 (2nd Cir. 1997), which rejected the challenge to Yale's housing policies that required students to live on campus on the grounds that these were fully disclosed before the students came to the campus.

¹³Image Tech. Servs. v. Eastman Kodak Co., 125 F.3d 1195 (9th Cir. 1997) (sustaining findings on liability and most of the plaintiff's \$71.4 million trial award). For a criticism of the narrow market definition and foreclosure rationale in *Kodak*, see HERBERT HOVENKAMP, THE ANTITRUST ENTERPRISE 98-102 (2005).

distinctive product, and thus offers no sign of any antitrust violation. What price discrimination there is can be eroded by the new entry of other patented drugs, subject of course to the entry obstacles that the FDA creates by its ever-increasing data demands for getting initial approvals. The market share question then has its own difficulties.

IV. ILLEGAL PRACTICES

The second point has to do with the various practices that are alleged to complete the monopolization claim. As a general matter, there is no agreement as to what kinds of practices between competitors should be regarded as appropriate and which should not. The best cases for monopolization cases often rest on common law wrongs. One example is that a firm that submits fraudulent evidence in order to procure a patent can be subject to a Section 2 action for blocking new entry into the marketplace.¹⁴ The complaint in *Tricor* goes to such a length, alleging that all of Abbott's patent defenses were not just wrong, but were sham.¹⁵ But it contains no allegations that the patent procurement itself was fraudulent within the meaning of *Walker Products*. It is worth noting that fraudulent applications should, in principle, also give rise to a common law tort of unfair competition, whereby the defendant's fraudulent behavior (on which the Patent and Trademark Office ("PTO") relied to issue the patent) has effectively disrupted ordinary contractual relationships, even if the antitrust plaintiff had no reliance of its own. Indeed, one general problem in monopolization is that once the argument moves beyond common

¹⁴*Walker Process Equipment, Inc v Food, Machinery & Chemical Corp*, 382 US 172, 176-77 (1965). I do not think that any want of plaintiff's reliance on the defendant's misrepresentations should matter in this context, as it would in the typical 10b(5) case in which the plaintiff claims to be harmed by the defendant's deceptive practices. *Walker Process* is a three party situation that is closer to the ordinary defamation case, where the reliance is never by the plaintiff but by the third party who refuses to do business with the defendant.

¹⁵*See Walgreen Complaint*, ¶¶ 30-34.

law wrongs, it is hard to develop a sensible typology of improper actions to fuel section 2 cases.¹⁶ This point has spawned enormous academic controversy. Here, it is useful to bring into the picture the Hatch-Waxman Act.¹⁷

V. HATCH WAXMAN

The Hatch-Waxman Act is a complex legislative compromise that seeks to coordinate the operation of the patent laws with that of the pure food and drug laws. One of the key points in the TriCor dispute turns on reasons for the 1984 Hatch-Waxman legislation. The plaintiffs offer a truncated version of the statute which talks about only one half of the deal, which is to get new generics into the marketplace as quickly as possible.¹⁸ In this regard two provisions are critical. First, the legislation allows the companies producing generics to test and use, but not to market, the patented drug before the expiration of the patent in order to facilitate the drug's rapid entry after the expiration of the patent. In addition, Hatch-Waxman grants a six month co-exclusivity period to the first party that files a so-called Paragraph IV proceeding. This filing undermines the power of the earlier patent by showing either that the patent is invalid or that its generic patent does not infringe the previous patent.¹⁹

¹⁶For discussion, see Richard A. Epstein, *Monopoly Dominance or Level Playing Field: The New Antitrust Paradox*, 72 U. CHI. L. REV. 49, 55-56 (2005).

¹⁷Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (codified in relevant part at 21 U.S.C.A. § 355).

¹⁸Walgreen Complaint ¶12.

¹⁹The four headings provide as follows: (I) patent information has not been filed; (II) the patent has expired; (III) the patent will expire on a specified date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. Id. § 355(j)(2)(A)(vii). Only the last heading gives co-exclusivity.

The other half of the overall picture is, however, every bit as important. The only way to have a steady rate of conversion to generics is to have a steady innovation rate of proprietary drugs. Hatch-Waxman took steps to remedy the perceived lag in new drug development by granting additional benefits to the patentee. Much simplified, the law allows any patentee an extension of its patent life as a partial offset to the time that the drug cannot be sold because it has not received the requisite FDA approval. Application of Hatch-Waxman, therefore, can extend the total patent life by periods up to five years. The Act also contains rules for automatic injunctions for up to 30 months to make sure that premature entry by generics does not smash the market. The point here is that once the generic is allowed to establish a toehold, it cannot be removed from the market if the generic sells large quantities at low prices—even if it is on the market only for a very short period of time. Hatch-Waxman contains no threshold showing of probable cause for the patentee to maintain its action, but only requires that it do so within 45 days after the generic announces its intention to enter the market.

Ironically, today Hatch-Waxman is no longer as effective as it was, because the ever longer period of clinical trials has shortened the effective period for drug use, so that today protection runs for as little as 11 or so years after a product reaches market. The key insight is that the patent law gives the exclusive right to sell, but it does not give an unconditional right to sell. All other licenses and permits have to be obtained before the product can be put into the marketplace, just as with non-patented products. In one sense, this is a crisis in medical innovation, but much of the high cost could be laid at the

doorstep of the FDA for its ever-expanding requirements for clinical trials, which are the counterpoint to Hatch-Waxman. The innovation side cannot be suppressed, and the conversion toward generics, which is praised as an unalloyed good in the retailer's complaint and in public debate, is properly recast as a complex tradeoff in which generic imitation carries with it its own costs in the form of reduced innovation. What is true in the general case is also true of TriCor. This background is critical to set the stage for the particular allegation of illegal practices.

VI. NEW GENERATION OF DRUGS

The first set of allegations states that the introduction of generic competition to TriCor was frustrated, delayed, and impeded by the strategic launch of new TriCor products. The complaint alleges that these were done “solely to switch users from one form” of TriCor to another, without any important medical benefit. The reason that the proposition was put in that categorical form is that the plaintiffs in this litigation did not want to get into an extended debate on just how much of the new innovation was meant to exclude competition versus how much reflected genuine product improvement, sometimes called “competition on the merits.” Saying that it is all one side and not the other makes it easy to avoid the question of trade-offs, which always slows down litigation and public debate.²⁰ If the public believes that all innovation is a subterfuge, pharmaceutical companies will constantly litigate into a head wind. Yet, by the same token, it has often noted how difficult it is to apply the antitrust law to new product

²⁰There is some authority that allows for predatory design cases, *see* C.R. Bard, Inc. v. M3 Systems, 157 F.3d 1340 (Fed. Cir. 1998), but these cases are not easy to win.

designs—think of the integrated products in the Microsoft litigation.²¹ The institutional shortcomings of courts on this matter show once again that antitrust law offers no cure-all.

There is also a second sense in which the Walgreen complaint overstates its case. The second generation drugs did receive a new patent. Following the usual rules of patent law, the PTO only grants patents to extensions of existing knowledge that are not obvious to individuals who are skilled in the relevant art. A patentee is not entitled to extend patent life by the use of artifice. The remark is true insofar as it goes, but it is wrong as applied to this case. The older patent expires when it expires, and its scope is not expanded by the introduction of the new patent, which gives protection only to the incremental advance after the earlier patent has expired. But so long as that patent holds up, it should not be relegated to second tier status. It gets full protection. Antitrust is not the forum in which to revisit the decisions made by the Patent Office.

On this point, one critical allegation in the complaint was that the 30 month stay triggered under Hatch-Waxman was used to forestall the introduction of the new generic for the 30 month period allowed under Hatch-Waxman.²² Abbott was manifestly aware of this provision when it decided to file its action against the two generic producers, Teva and Impax. It was equally clear that once the newer forms of TriCor had made it through the FDA, it abandoned the defense of these law suits. There is little doubt that the strategy delayed the entry of the generic, just as Hatch-Waxman provided it should. But the real question here is whether Section 2 should be used to override an essential

²¹United States v. Microsoft, 147 F.3d 935, 949-50 (D.C. 1998).

²²Walgreen complaint, ¶¶35-36.

component in the elaborate Hatch-Waxman compromise. In light of the enormous amount of energy that had been put into obtaining the original patent and FDA approval, Abbott's conduct does not fall within the framework of *Walker Process*, for Walgreen's complaint contains no allegation of fraudulent procurement of the original patent application.

At this point, therefore, the question is whether action that is legal under a specific statute can be found illegal under the antitrust law. The right answer to this question, I believe, is that the two statutes should operate in independent domains. If there is unhappiness with Hatch-Waxman, it should be modified to impose sanctions on those branded companies that are found to have wrongly invoked the 30-month stay. Getting a provision of that sort through Congress is no easy matter because it would fundamentally alter the terms of the original statutory compromise. But that is just the point. The internal balance under Hatch-Waxman is subject to much debate, including criticisms that the patent extensions it provides are too short, especially in light of today's ever-longer periods of clinical trials. But it is unwise institutionally to use the antitrust law to remedy the alleged defects in another statutory regime. That same question of integration also applies to the second key element of the Walgreen complaint, which involves delisting the capsule forms of TriCor from the National Drug Data File, ("NDDF").

VII. DELISTING FROM THE NDDF

The allegations about taking advantage of the 30 month stay are coupled with a second issue. What should be the effect of Abbott removing the initial version of TriCor

from the NDDF (which is a compendium of all the available drugs) with all the related descriptive and pricing information? The allegations in the Walgreen complaint noted that Abbott was not required to remove its product code for the discontinued capsules from the NDDF, even though it was allowed to do so.²³ It further noted that removing the product code for the discontinued capsules made it more difficult to order the generic substitutes because they could no longer be “referenced to a TriCor capsule code” which in turn made it more difficult for physicians to supply the generic equivalent.²⁴ The removal of the branded TriCor product from the list also changed the pricing for the generic drug, “because in the absence of a reference code for Defendants’ branded TriCor capsules,” the generic equivalent was now reclassified as a more expensive branded product which, in turn, carried higher co-pay and reimbursement rates to retail pharmacists under various physician drug plans.²⁵

The plaintiffs also alleged that Abbott supported its new tablet introduction by using the same clinical studies it had relied on to gain approval for its capsule form, which it was able to do because of the bioequivalence of the two products.²⁶ The effect of these various steps was said to prove that the “Defendant’s true goal was to interfere with and impede, to the greatest extent possible, generic competition,” which lies at the heart of a Section 2 violation.

Therefore, the key question in this suit is whether Abbott was under a duty to continue listing its branded capsule in the NDDF once it withdrew that drug from the

²³Walgreen complaint ¶37.

²⁴*Id.* ¶37, c.

²⁵*Id.* ¶37, d.

²⁶*Id.* ¶38.

market for its own business reasons. First, the initial listing was done pursuant to its business decision to list the drug in the NDDEF files in order to market the product. At the time of the original listing, moreover, Abbott enjoyed a monopoly position in the drug, which had yet to be challenged in any proceedings under the Hatch-Waxman Act (which provides detailed ways in which new generic drugs can enter the market by piggybacking on the information that the original branded company filed with the FDA).²⁷ It had, therefore, no reason to be tactical about its listing for exclusionary purposes, because when Abbott filed TriCor on NDDEF, it had no generic contenders to deal with.

The question is: Once a patent manufacturer decides that it will no longer market a product, does it have an antitrust duty to cooperate with generic competitors who wish to enter the market under the abbreviated review process set out under the Hatch-Waxman Act? On this issue, the key point to note is that antitrust law imposes duties to cooperate only under highly limited circumstances, such as those associated with the “essential facilities” doctrine, which imposes duties on holders of bottleneck facilities to deal with others. The obvious example is a railroad hub through which all lines run.

²⁷For some of the complications with the challenges, see, *Ranbaxy Labs. Ltd. v. Leavitt*, 373 U.S. App. D.C. 377, 469 F.3d 120, 126 (D.C. Cir. 2006); *Teva Pharmaceuticals, USA, Inc. v. Leavitt*, 548 F.3d 103 (D.C. Cir. 2008). These cases deal with the thorny question of when the first generic to enter the market is entitled to a six month co-exclusivity period with the original patentee. The gist of these rulings is that this period will be obtained only when the applicant files a Paragraph IV complaint that alleges that its product does not infringe a valid patent, or, alternatively, that the patent in question is not valid at all. *See supra*, note 19. From this it is said to follow that a branded company cannot withdraw its patents after the complaint is filed, but before it is resolved, in order to strip the initial party of its opportunity to get the six month co-exclusivity permission. Yet at the same time the patentee can withdraw the patent prior to any litigation, which blocks the paragraph IV filing—the only source of exclusivity—so that now the first new entrant must content itself with a paragraph I filing, for which no co-exclusivity is allowed. I do not think that these maneuvers could generate any antitrust liability under Section 2.

In practice, essential facilities cases are very rare under antitrust law.²⁸ And this conclusion is not true because the notion of an essential facility is incoherent. Indeed, this doctrine originated at common law, with respect to access to ports with no clear substitutes, or to exclusive franchises granted by the crown. The original case of *Allnut v. Inglis*²⁹ was a storage facility for goods bound to the export market for which the defendant had received an exclusive crown franchise. It could charge the standard rates, but not increase them to reflect the tax savings the shippers enjoyed when they used that facility. That case was easily resolved on the facts because there was a set of non-franchise rivals in the same line of business who charged competitive rates. These providers were not awarded a custom franchise by the Crown in order to control the risk of local abuse.

In modern times, however, the common law approach usually does not work, because once there is a bottleneck there is usually a system of direct common carrier regulation that is put into place to deal with the price issues. These cases raise complex pricing issues because typically the parties cannot draw easy comparisons to non-regulated firms. Administrative rate setting is the byword, and the usual attitude is that the antitrust law is a poor vehicle for rate setting, given the absence of any coherent institutional capacity to do so in the courts.³⁰ One notable exception is a case like *Microsoft*, where the linkages to the Microsoft operating system were all at zero price, so that all that was needed was an interconnection regime—and even that was made unduly

²⁸*Town of Concord v. Boston Edison Co.*, 915 F.2d 17 (1st. Cir. 1990).

²⁹104 Eng. Rep. 206 (K.B. 1810).

³⁰*Toys R US v. FTC*, 221 F.3d 928, 940 (7th Cir. 2000). In some cases rate setting provisions were found in antitrust consent decrees involving intellectual property.

complex in the most recent decision by Judge Kollar-Kottely on the point, which went overboard.³¹

The *TriCor* case does not have any network industry element. The strongest line of defense in my (tentative) view is to say that the NDDF and its customers can decide for themselves whether the decision to initially list a drug carries a contractual duty to continue its listing in order to facilitate the introduction of generic rivals in the market. In these cases, it is unlikely that any proprietary data base would seek to offend its key customers by imposing that condition. But if the Congress wishes to impose that duty by law, or to authorize the FDA to make some determination on this score, then there becomes a statutory basis for the duty (assuming that it passes constitutional muster), which obviates the need to rely on the antitrust laws to achieve the desired result. In the same vein, Congress could amend Hatch-Waxman to allow either the FDA or the Patent Office to take into account any perceived weakness or impropriety in relying on the 30 month automatic state which lies at the heart of the current statutory compromise. But it is doubtful, for example, that under its current statutory authority which goes to matters of health and safety, the FDA could today intervene on either the listing or patent issues, but not to the critical issues of patent validity, on which it now takes its cue from the patent office,³² or pricing, which is subject to complex regulations under other statutory regimes.

³¹New York v. Microsoft Corp., 531 F. Supp. 2d 141 (D.D.C. 2008).

³²See, *Teva*, 548 F.3d at 106-07, noting the dependence of the FDA on a report of the patent status by the holder of the NDA.

Once this framework is understood, it becomes hard to see how the decision to delist a drug from the NDDF can become the basis for a treble damage antitrust action. There are two ways to push this point. Both work in favor of Abbott, and both rest on recent Supreme Court developments. The first is to take the line in *Verizon Communications v. Trinko*³³ where the duties to interconnect under the Telecommunication Act were not held to create a duty that the antitrust laws could enforce under the Sherman Act. The case turned on a narrow substantive reading of *Aspen Skiing v. Aspen Highlands Skiing Corp.*³⁴ which had previously held that a group of ski resorts was subject to antitrust liability for pulling out of cooperative arrangements with other ski-lift suppliers in the Aspen market; a holding that receives today at best a frosty judicial welcome.³⁵

The argument carries over to this context. The right way to think about the antitrust law is to assume that it cannot piggyback on duties that come either from private contracts or other forms of regulation. In *Trinko* that inquiry took the following form: The elaborate interconnection obligations that Verizon had under the 1996 Telecommunications Act could not be used as a lever to create antitrust obligations for breach of those duties. Put otherwise, the scope of the interconnection obligations could be broader, but, if so, that breach could generate fines under the Telecommunications Act but not serve as a base for liability in an antitrust action. In the *TriCor* case, the plaintiffs have made no allegation of a breach of a statutory duty under the FDA, or even a breach

³³540 U.S. 398 (2004).

³⁴472 U.S. 585 (1985).

³⁵See e.g., The Department of Justice Report, *supra* at note 4, 120-126.

of contract between Abbott and the NDDF. At this point, the complaint is still weaker because there is no non-antitrust duty on which to peg the antitrust illegality. But even if antitrust duties were created by statute, or perhaps by contract, it would be a hard road to show that any breaches of those new duties would be relevant to the antitrust laws. The case for non-cooperation under Section 2 of the Sherman Act has to be built on a blank slate.

Thus we have to strip away all collateral matters, just as we strip away the telecommunication regulation, and ask this question: In a straight competitive industry, with no regulatory oversight, could any generic get a free ride on the information and trade name of the patented drug? The answer to that question, as a matter of intellectual property law, is that the generic could use the product if it was held that there was no infringement (as here) or that the patent was invalid. But the generic cannot use the trade name to promote the drug, and it cannot force the branded company to keep a listing for a product that the branded company no longer sells in order to make the generic's position easier. The listing practices on the NDDF should not alter the balance that is created under the antitrust or the IP law, so that cases like *Trinko* should be dispositive in favor of Abbott.

In addition, two features of *Trinko* are worthy of further note. First, the Telecommunications statute contains a provision that explicitly preserves the application of the antitrust laws. Second, as an antitrust case the *Trinko* decision involved an exotic theory about the refusal to aid competitors, in this instance by supplying various

components (the unbundled network elements or “UNEs”) at below market prices.

The more recent case of *Credit Suisse Securities v. Billings*³⁶ involved the interaction between the securities and the antitrust law, and there the role of antitrust law was diminished still further. The Court took the position that there was an implied ouster of the antitrust law, given that the officials in charge of enforcing the securities law thought that *any* antitrust action—regardless of its soundness under the Sherman Act—with respect to underwriting practices was ill-advised. That case seemed to hold that once the securities regulators took over the field, the antitrust law fell to the side, without any case-specific showing made in *Trinko* that the antitrust law case failed on its own merits. *Credit Suisse* marks a real departure from earlier law, which tended to favor the view of peaceful coexistence between the two systems, so that it was possible, as in *Trinko*, to succeed if the *Aspen* antitrust duties had any traction against Verizon.

These points could be important should the issue raised in the TriCor litigation be subject to some direct form of regulation, say through the FDA. Under *Trinko*, the plaintiff could only succeed if it could be shown that the statute wanted its new listing duties to ground antitrust suits by competitors, which it could explicitly provide. Otherwise, the basic *Aspen* standards should be narrowly construed as they are in *Trinko*, which appears to be the superior normative approach in all Section 2 cases.

VIII. CONCLUSION

The purpose of this short article is to argue the proposition that the various schemes of legal rights and duties should be applied separately and independently, unless

³⁶127 S. Ct. 2383 (2007).

there is some specific textual warrant for their interaction. The point is of ever greater importance in modern settings because complex industries are typically subject to multiple schemes of regulation. Pharmaceuticals are one key example. And the orderly administration of the system as a whole means, I believe, that antitrust, patent, FDA, and contract duties should be kept in their respective spheres unless there is some explicit textual authorization for their integration.