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Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored

Kelly Smith & Jonathan Gleklen
Arnold & Porter LLP

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I. INTRODUCTION

A striking aspect of the Third Circuit's decision on Hatch-Waxman patent settlements in the K-Dur litigation[2] is the panel's repeated reliance on conclusions that the Federal Trade Commission ("FTC") has drawn from internal studies. It is hard to get through the opinion without running up against "a 2010 analysis by the FTC found," a "2002 study conducted by the FTC concluded that," or a "[d]ata analyzed by the FTC suggest," leading up to a "we agree . . . with the FTC that."[3]

We leave to others the issue of due process in relying on an advocate's characterization of evidence it has shared with no one else. We focus instead on an FTC finding that neither the Court nor, to our knowledge, anyone else has noticed. According to the FTC, the structure of the Hatch-Waxman Act creates economic incentives for generic drug makers ("Generics") to mount extraordinarily thin patent challenges. A rational Generic, the FTC tells us, would challenge the patents protecting nearly 90 percent of the branded drugs sold in the United States (as measured by wholesale dollar sales) if it were the first to do so (a "first filer") and it had even a three percent chance of success. Or to put it another way, a rational Generic company executive who is told by his lawyers that he has on the order of a 95 percent chance of losing, should respond, "Great! Challenge the patent."

This surprising finding is buried in the Federal Trade Commission's 2011 Authorized Generic Report.[4] We say "buried" because it is most clearly asserted in a footnote in the Executive Summary and is "disclosed" in the body of the report most plainly as follows[5]:

$$\text{Profit} = \frac{(\hat{p}_g - 0.1) \times \hat{r}_g \times r_b}{2 \times \hat{p}_g}$$

[1] Kelly Smith is an associate and Jonathan Gleklen is a partner in the Washington, D.C. antitrust practice of Arnold & Porter LLP.

[2] In re K-Dur Antitrust Litig., 2012 WL 2877662 (3d Cir. July 16, 2012).

[3] *Id.* at *6, *13, *15-16.

[4] Fed. Trade Comm'n, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (Aug. 2011), *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf ("FTC Report").

[5] *Id.* at 110. Talk about a riddle, wrapped in a mystery, inside an enigma.

II. THE FTC'S AUTHORIZED GENERIC REPORT

The Authorized Generic Report was almost six years in the making and rested on data requested from 118 pharmaceutical companies.[6] It was undertaken at the behest of Congress to look at whether a Branded company's launch of generic versions of its branded drugs ("authorized generics" or "AGs") might give reason for the generic industry to stay away from investing in generic drugs and jeopardize the vitality of the industry in the long term.[7]

The FTC's report was released on August 31, 2011. The conclusions reached were not surprising. The FTC did not conclude that less competition (banning authorized generics) would be a good thing. And, although no one had asked, it added the thought that drug industry patent settlements in which the Brand agrees not to launch an AG were bad.[8] Given the end of August timing, and the eminently predictable conclusions, the antitrust world took little notice. Those practitioners who were not already on vacation packed for the Labor Day weekend, left town, and—apparently—did not read the FTC Report when they came back. Lost in the process was the fact that while the overall conclusion was not remarkable, the analysis supporting it was.

The question posed to the Commission was whether competition from an AG would reduce the incentive for a first filer to challenge the innovator's patent and, if so, by how much. The unsurprising answers were "yes" and "not by much"[9] even in the case of drugs with relatively small sales levels. What was hidden in that answer was the magnitude of such incentives whether or not an AG is expected, particularly with respect to drugs with significant sales. A footnote to the report gives the only specific numbers, and, as noted, they relate to drugs with small sales:

> [F]or a drug with [annual] brand sales of $130 million, a generic that does not anticipate AG competition will expect a patent challenge to be profitable if it has at least a 4 percent chance of winning; with AG competition, that generic would need at least a 10 percent chance of winning to expect a patent challenge to be profitable.[10]

The FTC said that for drugs with larger sales, the likelihood of winning necessary to make a challenge rational was even less, but it did not specify the break-even numbers for those levels. The reader was left to squint at the following graph, which uses a logarithmic scale on the horizontal axis, to determine what those numbers were.[11]

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[6] *See* Fed. Trade Comm'n Notices, 71 Fed. Reg. 16779-02, 16783 (Apr. 4, 2006) and Fed. Trade Comm'n Notices, 72 Fed. Reg. 25304, 25314 (May 4, 2007).

[7] *Id. See also* Press Release, Generic Pharm. Ass'n, GPhA Welcomes FTC's Consideration of Authorized Generics Study: "Authorized Generics" Undermine Incentive to Produce Affordable Medicines (May 12, 2005), *available at* http://www.gphaonline.org/media/press-releases/2009/gpha-welcomes-ftcs-consideration-authorized-generics-study-authorized-gene.

[8] Press Release, Fed. Trade, Comm'n, FTC Report Examines How Authorized Generics Affect the Pharmaceutical Market, (Aug. 31, 2011), *available at* http://www.ftc.gov/opa/2011/08/genericdrugs.shtm.

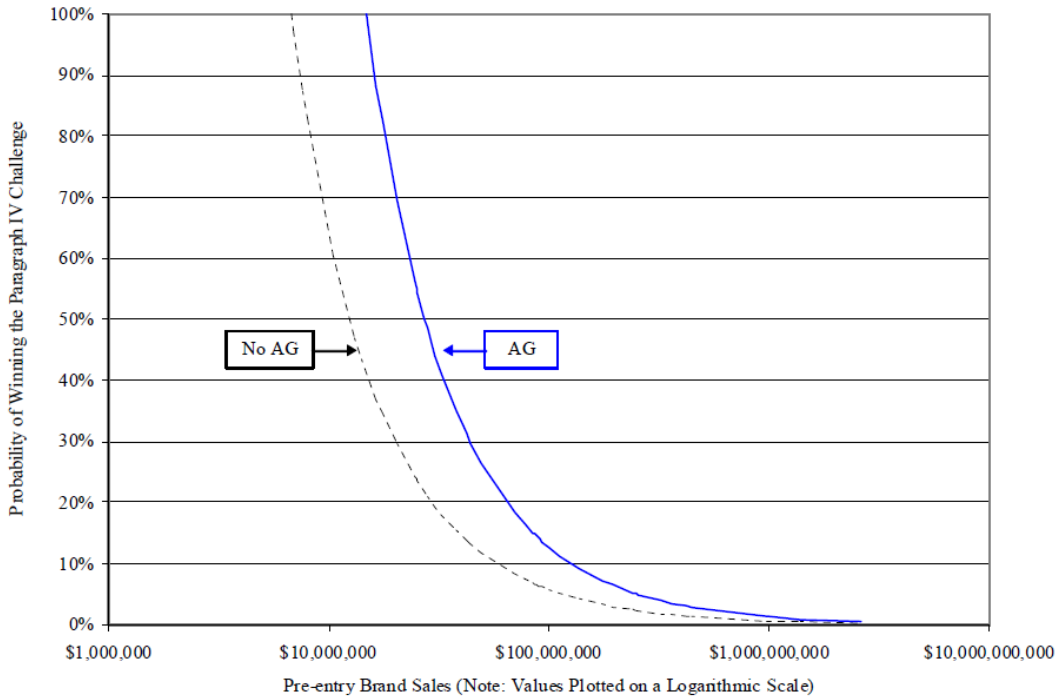
[9] FTC Report, Ch. 6 at 115-19.

[10] FTC Report, Exec. Summ. at iii n.7; *see also* Ch. 6 at 116, 118.

[11] The use of a logarithmic scale means that more than half of the horizontal space in the graph is devoted to drugs with annual sales of less than $100 million, *i.e.*, drugs that account for less than 3 percent of dollar sales. The remaining 97 percent of sales are crammed into the other 40 percent or so of the horizontal space. This was a proper choice of scale given the point the Bureau of Economics was making: that even at extremely low sales levels the effect on incentives is too small to worry about.

Figure 1:

Figure 6-6: Break-Even Market Sizes for Varying Probabilities of Successful Paragraph IV Challenge



The chart shows that the probability of success required to justify a patent challenge is—literally—vanishingly small as the volume of Branded company sales exceeds $100 million.

How small?[12] The FTC Report explains how it calculated the break-even number at the $130 million level,[13] and we used the same methodology to estimate the likelihood of success that would make a patent challenge by a first filing Generic rational at other levels of sales. The results are set out below. [14]

[12] *Cf.* ARTHUR (Orion Pictures 1981) ("It's terribly small, a tiny little country. Rhode Island could beat the crap out of it in a war. That's how small it is.").

[13] FTC Report, Ch. 3 at 33-63 and Ch. 6 at 93-118.

[14] The FTC Report focuses on branded drugs that first experience generic entry during the study period (2003-2008). Our references to branded drug sales parallel this usage.

Table 1			
Pre-Generic Entry Annual Sales[15]		**Minimum Probability of Win to Justify Challenge**	
Millions	*Cumulative %*	*Without AG Entry*	*With AG Entry*
$129	97%	4.4%	9.9%
$232	93%	2.5%	5.4%
$454	88%	1.3%	2.8%
$792	77%	0.7%	1.6%
$1,800	51%	0.3%	0.7%
$5,500	<1%	0.1%	0.2%

To the extent one is tempted to consider adjustments to the FTC's analysis, the result becomes even stronger. The FTC Report observed that cost of litigation "[e]xpenditures ranged from very low amounts to many multiples of the $5 million mean, and the inter-quartile range was roughly $2 million to $6 million."[16] Nonetheless, the FTC's calculations use a constant litigation cost of $5 million regardless of the size of Brand sales. If one assumes that a rational Generic would devote fewer resources to a patent challenge for a lower selling drug, and more for a challenge on a Brand with huge sales, the range of minimum probability of percentages narrows. That is because adjusting the litigation expense assumption means the likelihood of success at which it is rational to challenge patents goes down on branded drugs with smaller sales and goes up, but just a little, for drugs with large sales. The table below shows such an adjustment.

Table 2				
Pre-Generic Entry Annual Sales		**Assumed Cost of Litigation***	**Minimum Probability of Win to Justify Challenge**	
Millions	*Cumulative %*	*Millions*	*Without AG Entry*	*With AG Entry*
$129	97%	$2	1.8%	4.0%
$232	93%	$5	2.5%	5.4%
$454	88%	$5	1.3%	2.8%
$792	77%	$5	0.7%	1.6%
$1,800	51%	$10	0.6%	1.4%
$5,500	<1%	$25	0.5%	1.1%

*Adjusted from the FTC-Assumed $5 Million Litigation Cost

[15] As in the FTC Report, we analyze challenge incentives based on pre-generic entry annual wholesale sales for all drugs first experiencing generic entry in 2003 through 2008, where sales are aggregated over strength and dosage form (i.e., all strengths and forms of a particular combination of active ingredients).

[16] FTC Report, Ch. 6 at 111.

What these tables show is that a rational Generic company would challenge patents on drugs accounting for 90 percent of pharmaceutical sales if it had a likelihood of success in the low to mid-single digits.

III. HOW CAN THIS BE?

The results that we derive from the FTC Report's analysis are so extreme as to prompt a question as to whether they can be right. The explanation is straightforward. In the usual case, an enterprise is free to sell a potentially infringing product without permission from the FDA or any other government agency. But doing so carries a risk. A decision to sell product in the face of a patent exposes the company to a suit for damages. The company will not take the risk unless it has considerable confidence in its ability to succeed. True, a potential infringer can, under certain circumstances, anticipate a patent challenge by filing a declaratory judgment action, but that is the exception, not the rule.[17] Absent a declaratory judgment, the risk of damages means that rational economic actors will not go up against a patent without some appreciable chance of success.[18]

The Hatch-Waxman Act swept away that self-policing mechanism in the generic drug context. It makes the filing of an Abbreviated New Drug Application an artificial act of infringement that permits litigation of the validity of the patent long before the infringing product is sold and thus long before any damages accrue.[19] In this setting, taking a shot at a patent is, if not costless, quite cheap. The only costs of a challenge are litigation expenses and the cost of regulatory approval.[20]

The cautionary effect of a damages claim on willingness to challenge a pharmaceutical patent is well recognized. Indeed, for many years it was conventional wisdom that generic firms would not launch their products "at risk," i.e., they would not launch before a final judgment

[17] To maintain a declaratory judgment suit, a party "must show that the dispute is "definite and concrete, touching the legal relations of parties having adverse legal interests;' and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character.'" MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007) (citing Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240-41 (1937)).

[18] Third parties can challenge issued patents via an *inter partes* review proceeding before the United States Patent and Trademark Office ("PTO") as to prior art without exposing the challenger to infringement damages. 35 USC § 311-318. Moreover, a challenge at the PTO does not face the presumption of validity that applies in a court proceeding. *In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008). Despite these advantages, it is rare for there to be an *inter partes* challenge to drug patents, or so we are told by senior in-house lawyers at several leading research-oriented drug companies. Provisions of the Patent Reform Act of 2011, which go into full effect after March 2013, will broaden the grounds for invalidity that can be raised in the PTO after patent issuance, creating a Post Grant Review proceeding that can include grounds such as written description, enablement, and indefiniteness. 35 USC § 321(b). We doubt that these changes will expand the number of PTO challenges, in part because proceedings based on these additional grounds must be brought within nine months of the patent's issue, 35 U.S.C. § 321(c), a time that would likely come before the Brand's marketplace success (or failure) is known.

[19] 35 U.S.C. § 271(e)(2).

[20] The data in Table 2 show that the risk of sanctions under Rule 11 or otherwise will not appreciably change the incentives. Even if we double the cost of litigation that the FTC used to reflect the cost of potential judicial sanctions against the Generic, the break-even likelihood of success that makes a challenge rational remains in the single digits.

removed the risk of paying damages.[21] This is reflected in amendments to the Hatch-Waxman Act that make clear that, while a first filer will forfeit its 180-day exclusivity period if it does not begin marketing within 75 days after a court ruling, it is the appellate result, not the trial court result, that counts.[22] The concern was that a Generic that prevailed in the trial court was not likely to launch the product and face the risk of damages if there were a chance of reversal on appeal. Hence, the exclusivity period starts to run only with affirmance by the Federal Circuit.

The FTC's analysis shows that, with no risk of damages, there is every incentive for thin challenges to drug patents. The Eleventh Circuit recently described patent litigation as "infamously costly and notoriously unpredictable." It noted that "[e]ven the confident patent owner knows that the chances of prevailing in patent litigation rarely exceed seventy percent."[23] Thus, when a drug with an appreciable level of sales is involved, it is economically rational to challenge the patent virtually regardless of grounds to believe the patent is infirm. Things may turn up in discovery, and courts and juries are known to make mistakes.[24]

IV. CONCLUSION

A court that is willing to accept and rely on FTC reports based on nonpublic information has little reason to question the FTC findings set out above. What those findings tells us is that if conduct follows incentives—a typical conclusion in antitrust jurisprudence—courts will be asked to consider more pharmaceutical patent challenges than they should, including cases with a vanishingly thin likelihood of success. In a setting where, the FTC tells us, we should expect a plethora of "file and see what happens" patent challenges, courts should at least think a while before imposing rules that could limit the ability of parties to weed out those cases by settlement.

[21] *See, e.g.*, *Paying off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited,* Hearing before the Senate Committee on the Judiciary, 110th Cong., (Jan. 17, 2007) at 24 ("[W]e [Barr] do not bring products to market in the face of a patent because of the damages we risk."). *But see* Joseph M. O'Malley, Jr., et al., *Failure to Launch,* Intellectual Property 30 (April 2011).

[22] *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

[23] FTC v. Watson Pharm. Inc., 677 F.3d 1298, 1313 (11th Cir. 2012) (quoting In re Ciprofloxacin Hydrochloride Antitrust Litigation 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003) ("No matter how valid a patent is—no matter how often it has been upheld in other litigation . . . it is still a gamble to place a technology case in the hands of a lay judge or jury. . . .") (alterations and quotation marks omitted)).

[24] In one Hatch-Waxman case, the decision to launch a generic version of a patented drug was based solely on profit potential, without consulting a patent lawyer and without review of the file history of the patents at issue. Glaxo Grp. Ltd v. Apotex, Inc., 268 F. Supp. 2d 1013, 1022-23 (N.D. Ill. 2003), *aff'd in part, rev'd in part*, 376 F. 3d 1330 (Fed. Cir. 2004).