Generic Competition in Transgenic Soybeans

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I. The High Stakes Game of Generic Competition

In 2010, the U.S. Department of Agriculture (USDA) and U.S. Department of Justice (DOJ) jointly conducted five workshops as part of the initiative "Agriculture and Antitrust Enforcement Issues in our 21st Century Economy." The day-long sessions in Iowa, Alabama, Wisconsin, Colorado, and Washington D.C. reminded us that agriculture remains a critical part of the economic, social, and cultural fabric of the U.S. But a number of concerns came through clearly. These include: consolidation and dominant firms in key parts of the agricultural supply chain; the role of intellectual property (IP) in the transgenic (i.e., genetically modified) seed industry; monopsony power in meat, poultry, and milk processing; and increasing concentration in food retailing.

Many observers left the USDA-DOJ workshops asking how policy can be realigned to address what are recognized as serious and systemic competitive problems in the U.S. agricultural

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supply chain. Ultimately, it is the growers and consumers of agricultural products that bear the brunt of these problems in the form of non-competitive prices, lower quality, compromised safety and reliability, less choice, and reduced innovation. One of the many competitive issues addressed at the workshops is the intersection of competition law and IP protection in markets for genetic traits and transgenic seed for crops such as soybeans, corn, and cotton. While this issue has been debated for years in seed and elsewhere, the prospect of benefits from generic competition has galvanized the industry.

The test case is the potential for a generic trait for soybean tolerance to the herbicide glyphosate. Monsanto's patented Roundup Ready® (RR®) trait, contained in transgenic soybeans and planted widely in the U.S. and abroad, goes off-patent in 2014. This has two immediate implications. First, growers will not pay a premium to plant RR® soybeans. Second, biotechnology developers ("biotechs") and seed companies (collectively referred to as "generic rivals") may produce the trait in generic form and combine or "stack" it with other traits in new seed products. Much like generic pharmaceuticals, the transition to generic competition in RR® soybeans is critically important for growers, who could benefit from increased choice and lower prices. However, a properly structured transition plan to facilitate generic competition does not seem close at hand, increasing the risk that the industry will "miss the window." The costs of failure are high for competition and consumers, and for the health of the U.S. agricultural sector overall. Moreover, developing an effective approach to promoting generic competition in RR® soybeans should ideally serve as a template for other traits that are due to come off-patent in the future, punctuating the importance of getting the process right the first time.

This White Paper sets out the major issues in the debate over the development of generic competition in genetic traits for soybeans. It consists of five parts: (1) the benefits of generic transgenic soybeans; (2) the likely effect on generic competition of competitive problems in the

genetic traits markets; (3) the importance of securing a path to market for generic traits; (4) what is missing from the current industry approach; and (5) policy priorities.

II. Summary of Major Points

- ***Generic competition in transgenic soybeans has significant potential to bring benefits to growers and ultimate consumers.*** The widespread adoption of transgenic soybeans means that the benefits of generic competition will be commensurately broad. Moreover, stacked genetic traits are becoming the market standard in transgenic soybeans and will be facilitated by generic competition.
- ***Competitive problems in the markets for genetic traits pose a challenge to the development of generic competition.*** Because the patent-holder on RR® dominates the markets for genetic traits and has a patented successor trait – Roundup Ready 2 Yield (RR2Y®) already in play – it is potentially more difficult for generic rivals to bring products containing the generic trait to market within the window of time necessary to gain a foothold.
- ***A clear path to market for firms developing transgenic soybeans containing the generic RR® trait requires certainty and timing.*** Certainty results from a known process by which generic rivals can engage in R&D before and after patent expiration to secure needed regulatory approvals for transgenic products. Products containing a generic trait must also be ready for market at the same time RR® goes off-patent.
- ***Two forms of IP "access" are essential for R&D on new generic transgenic soybean products to move forward.***
    - ***The rights to stack ("stacking rights") RR® with other complementary traits is needed before patent expiration.***

- *Access to data on* RR® *is needed before and after patent expiration.*

  Without such IP access, in exchange for fair compensation to the patent-holder, generic rivals will be forced into the costly process of recreating data and beginning R&D on stacking generic RR® with other traits *after* patent expiration. These impediments and delays will stall the progress of generic competition.

- *A successful transition to generic competition in transgenic soybeans requires a structured, transparent, and enforceable policy.* Developing a process by which rivals are able to perform R&D to develop new products containing the generic RR® trait before and after patent expiration is critical. While the role of the patent-holder is integral to this process, its natural incentives to impede generic competition require more than assurances and commitments on the part of the patent-holder.

- *At least two policy priorities for promoting generic competition in* RR® *soybeans are clear.* One is an independent process, backstopped by a legislative agenda, for developing transparent and enforceable terms and conditions for the IP access necessary to conduct R&D with the generic trait. A second priority is antitrust enforcement to resolve fundamental competitive issues surrounding the appropriate use of IP, versus strategic competitive use of IP that potentially harms competition and consumers.

III. The Benefits of Generic RR® Soybeans

Transgenic seed has been genetically modified to contain certain desirable traits. "Input" traits affect the agronomic performance of plants, including tolerance to herbicides (Ht traits) and resistance to certain insects (Bt traits). "Value-added" traits affect the characteristics of a plant's

output, such as corn with superior amino acid balance and soybean oils with more shelf life.[2] Some transgenic seed contains a single genetic trait. But traits also appear in stacks or combinations with other Ht, Bt, or value-added traits. Stacking genetic traits solves a number of problems. These include providing multiple modes of action to combat growing resistance of weeds or insects to plants containing agronomic traits, and efficiently combining agronomic and value-added traits.

Transgenic varieties containing a single Ht trait currently account for 94 percent of all soybean acres planted in the U.S.[3] In some states, such as South Dakota and Mississippi, this portion is as high as 98 percent.[4] The market for Ht soybean traits is highly concentrated as a result of Monsanto's sizable 97 percent market share.[5] There are five trait "profiles" for soybeans on the market, many fewer than the 29 profiles for corn and the 11 for cotton. Four of the five profiles are single Ht soybean traits, available from Bayer (LibertyLink®), Monsanto (RR® and RR2Y®), and DuPont (STS®).[6] Stacked traits in soybeans account for only 20 percent of total trait profiles - far less than in corn and cotton, where they account for 75 and 55 percent of total profiles,

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[2]Marvin L. Hayenga, "Structural Change in the Biotech Seed and Chemical Industrial Complex," 1 AGBIOFORUM (1998) 43, at p. 48.

[3]Traits are available for tolerance to the herbicides glyphosate, glufosinate, and sulfonyhurea.

[4]"Acreage," U.S. Department of Agriculture, National Agriculture Statistics Service, Agricultural Statistics board (June 30, 2011), at pp. 25-27. Available http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2011.pdf.

[5]2008 soybean and corn trait shares obtained from Carl Casale, "Morgan Stanley: Global Basic Materials Conference 2009," (February 18, 2009). Available originally at http://www.monsanto.com/pdf/investors/2009/02_18_09.pdf. See also Brett Begemann, "Goldman Sachs Agricultural Biotech Forum," (February 12, 2008). Available originally at http://www.monsanto.com/pdf/investors/2008/02-12-08.pdf. These pages have either been removed or relocated on the Monsanto.com website. Original versions are available from the author.

[6]Vandy Howell and Jonathan Gleklen, "Competition and Innovation in American Agriculture: A Response to the American Antitrust Institute's "'Transgenic Seed Platforms: Competition Between a Rock and a Hard Place?'" report submitted on behalf of Monsanto in the USDA-DOJ hearing on "Agriculture and Antitrust Enforcement in our 21st Century Economy," (December 31, 2009), at pp. 56-59.

respectively.[7] This disparity is due to the fact that transgenic soybeans largely incorporate single Ht traits. However, stacking is becoming more prevalent in soybeans. The fifth soybean trait profile is a stack containing DuPont and Monsanto traits (RR®-STS®). Another stack with DuPont and Monsanto traits is under development (Optimum GAT®-RR®).[8] Monsanto's investor documents also show a stacked trait soybean product in the company's longer-term R&D pipeline.[9]

The foregoing snapshot of transgenic soybeans highlights two important facts. First, the widespread adoption of transgenic soybeans means that the benefits of generic competition are likely to be commensurately broad. Growers and the ultimate consumers of soybean products stand to benefit significantly from the lower prices, increased choice, and innovation that generic competition will likely bring. Second, as indicated by research and products in the pipeline, stacked traits are becoming more common in transgenic soybeans, a trend that will be facilitated by generic competition.[10] A generic RR® trait will make it easier for rivals to stack, spurring competition and creating choices for growers.

IV. The Competition Debate

The simmering debate over competition in transgenic seed was ignited only recently. Stakeholders have communicated the urgency of competitive issues to agriculture regulators, antitrust enforcers, and industry participants. These include comments filed in the USDA-DOJ

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[7]On the basis of acreage actually planted with stacked trait transgenic seed, the numbers are slightly different (58 percent for corn and 49 percent for cotton). This difference results from the fact that some trait profiles are more popular than others. *See supra* note 4.

[8]*Supra* note 6, at p. 55. DuPont's Optimum GAT trait has been the subject of ongoing patent infringement and antitrust litigation.

[9]Kerry Preete, "Goldman Sachs Agricultural Biotech Forum 2011," (February 9, 2011), at p. 16. Available http://www.monsanto.com/investors/Documents/2011/Goldman_Sachs_Presentation.pdf.

[10]See, e.g., Alan R. Gould, "Have I Got a New Trait for You!" Verdant Partners (August 5, 2009). Available http://www.verdantpartners.com/trait.php.

agricultural workshop initiative, panel discussions at the workshops, White Papers issued by the AAI in 2009 and 2010,[11] several press articles, and industry letters setting forth the major issues relevant to the transition to generic competition. An investigation into Monsanto's business practices involving transgenic seed was also initiated by the DOJ in early 2010, and appears to be pending.

The debate highlights the intersection between antitrust law, which protects competition, and IP protection, which promotes innovation. In transgenic seed, the debate revolves around the unresolved question of what conduct falls legitimately within the scope of a patent and what does not - particularly strategic behavior designed to influence, shape, or control competition under the guise of IP protection.[12] The highly concentrated market structure for generic traits exacerbates this problem. For example, Monsanto has about 97 percent of the market for Ht soybean traits, 95 percent of the market for Bt and Ht traits, and, on average, 75 percent of the market for Bt and Ht corn traits.[13] The most important implication of this market dominance is that rival biotechnology developers, seed companies, and growers have relatively few choices in products that *do not* contain Monsanto traits. Because of limited choice, market participants are therefore unduly affected by the constraints placed on the use of Monsanto technology.

If and how Monsanto traits can be stacked with rival traits is the central question for competition. For example, the competitive importance of stacking was recognized by the DOJ when

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[11]*See* Diana L. Moss, "Transgenic Seed Platforms: Competition Between a Rock and a Hard Place," American Antitrust Institute (October 2009). Available at http://www.antitrustinstitute.org/archives/files/AAI_Platforms percent20and percent20Transgenic percent20Seed_102320091053.pdf. *See* also Diana L. Moss, "Transgenic Seed Platforms: Competition Between a Rock and a Hard Place: Addendum," American Antitrust Institute (April 2010). Available http://www.antitrustinstitute.org/sites/default/files/Addendum%20to%20AAI%20White%20Paper_Transgenic%20Seed.4.5_040520101107.pdf.

[12]The history of transgenic seed contains numerous antitrust claims relating to IP, including monopolization issues. *See*, e.g., *American Seed Co., Inc. v. Monsanto Co.*, 238 F.R.D. 394 (D. Del. 2006) and antitrust counterclaims articulated in *Monsanto Co. v. Syngenta Seeds, Inc.*, 443 F.Supp.2d 648 (D. Del. 2006).

[13]See *supra* note 5.Cotton shares also derived from data complied from "Cotton Varieties Planted - 2009." U.S. Department of Agriculture, Agricultural Marketing Service, Cotton Program.

it required Monsanto to remove anti-stacking provisions in its licensees as part of its 2007 merger with cotton giant Delta and Pine Land.[14] Two-thirds of the trait profiles for corn, soybeans, and cotton involve stacks. To stack traits, a generic rival has three options: (1) stack its own traits, (2) stack its trait with the trait of another rival, or (3) stack its trait with a Monsanto trait. However, the first two options are limited because smaller rivals have many fewer Ht and Bt traits to stack. Most viable stacking opportunities therefore lie in combining non-Monsanto with Monsanto traits.

That most stacked trait profiles contain a Monsanto trait reflects the biotech's dominance in the genetic traits markets. And while Monsanto has emphasized its policy of broadly licensing its technology to rivals, it is not incumbent upon the firm to license its technology to all comers or allow all forms of stacking. It is also possible for the firm to selectively license its technology or to encourage growers to adopt a successor technology to the trait going off-patent. In a competitive market for genetic traits, these questions would garner less attention. However, in a highly concentrated market dominated by a single patent-holder with a successor technology in play, they attract more scrutiny. Many of these issues will not disappear when RR® goes off patent in 2014, posing a challenge for generic competition.

V. Securing a Path to Market for Generic Traits

Generic competition in R&D- and regulation-intensive technologies does not sprout up overnight. Most R&D expenditures involving plant biotechnology are incurred in the first stage of production, plant breeding, and account for about 40 percent of the final seed price.[15] Development of commercial varieties of transgenic seed involves long lead times and regulatory approvals from

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[14]Together with the divestiture of germplasm and seed assets, these requirements together were designed to ensure that rivals had access to the technologies needed to bring new transgenic cotton products to market. *See U.S. v. Monsanto Company and Delta and Pine Land Company*, Proposed Final Judgment, Case: 1:07-cv-00992 (May 31, 2007). Available http://www.justice.gov/atr/cases/f223600/223679.htm).

[15]Jorge Fernandez-Cornejo, "The Seed Industry in U.S. Agriculture," U.S. Department of Agriculture, Economic Research Service, Agriculture Information Bulletin No. 786 (2004), at p. 29.

the USDA, Food and Drug Administration, and Environmental Protection Agency. Overall, the process of developing new varieties can span 10 to 15 years.[16] While less time may be needed to develop stacks containing a generic RR® trait, a clear path to market is nonetheless essential to induce the investment needed to promote generic competition.

Certainty and timing are the central elements of a path to market. Certainty comes from a known process for rivals to engage in the R&D necessary to produce commercially viable products containing generic RR®, including obtaining regulatory approvals. A key element of certainty is the process for registering a generic trait – alone or in stacks – in countries that import transgenic seed. Because grain destined for the export market is not segregated from that remaining in the U.S., any uncertainty regarding foreign registrations will also affect domestic production decisions. If the generic RR® trait appears singly in transgenic soybeans, post-patent maintenance of foreign registrations by the patent-holder is likely to be sufficient to ensure that soybeans will continue to be accepted into the grain channel.

As a general matter, generic competition depends on cooperation between the patent-holder and generic rivals. Cooperation is particularly important in genetic traits markets where the patent-holder holds a substantial market share and stacked traits are the market standard. Arguably, it is also the responsibility of the patent-holder to serve as "steward" of the technology as it comes off-patent and the generic phase begins. Cooperation is based on two major forms of IP access, in exchange for fair compensation to the patent-holder: (1) on-patent stacking rights and (2) on-patent *and* post-patent access to data.

As discussed in the previous section, stacking rights remains a contentious issue. A number of data access scenarios are possible. For example, rivals developing stacked trait soybean products

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[16] *Supra* note 16, at p. 51. See also *U.S. v. Monsanto and Delta and Pine Land*, Complaint, (Case No. 1:07-cv-00992, D.D.C) (May 31, 2007), at PP. 15.

containing generic RR® will, at a minimum, require a regulatory letter of access from the patent-holder. This will allow generic innovators to cite to the data that support how the trait performs and its impacts on humans, animals, and the environment. In other cases, foreign regulators might require access to the entire RR® data package to allow generic rivals to secure foreign registrations for stacked trait products. Finally, in countries without a regulatory framework for the importation of transgenic seed, access to the patent-holder's data packages for RR® will be required to secure foreign registrations for the generic trait.

Data packages for the trait going off-patent are therefore a critical input for rivals attempting to bring stacked products containing the generic trait to market. Because data do not become publicly available upon patent expiration, access to such data remains an important component of R&D conducted before and after patent expiration. Without access to data, rivals would need to recreate it – a costly and socially inefficient process that would delay generic competition.

Timing is also important for facilitating generic competition. A generic trait must be ready for market or at the same time the incumbent technology goes off-patent. Given the lead times involved, this means generic rivals would need to start the generic trait R&D process before patent expiration in 2014. Without advance access, there would be a gap between the time the trait goes off-patent and when the products containing the generic trait become available. Gaps promote the lock-in of successor technologies and forestall generic competition. Because growers often display brand loyalty, make planting decisions in advance, and can incur high costs to switch between brands due to consumer incentive programs, ensuring that a generic trait will be ready for market at the time of patent expiration is critically important.

In sum, a generic product is expected to compete with other products to determine its commercial viability. However, a level playing field is needed to promote generic competition. The

failure to develop a transparent and enforceable approach by which rivals can gain access to stacking rights and data for RR® will create significant barriers to entry in generic trait markets.

VI. What is Missing from the Current Approach?

Steps have already been taken to create a transition to generic competition in transgenic soybeans. In December 2009, Monsanto announced a policy on patent expiration for the RR® soybean trait. The major component of the policy that addressed generic competition was a commitment to provide "full global regulatory support" (i.e., to maintain foreign registrations) for RR® through 2017.[17] In mid-2010, the commitment was extended to 2021.[18] Another component of the 2009 policy spelled out the conditions that would normally be expected to apply upon patent expiration, including that the patent-holder would: (1) stop collecting royalties and enforcing prohibitions on seed saving or other requirements to destroy seed, and (2) allow farmers to continue to plant seed with RR® (even if they also plant seed with RR2Y®) and universities to continue breeding with RR®. A final part of the policy spelled out the patent-holder's commitment to forbear from enforcing variety patents against farmers that save seed containing RR®. Arguably, however, since Monsanto is actively promoting RR2Y® instead of RR®, this commitment is unlikely to have much impact.

Monsanto's policy brought forth responses from a variety of stakeholders, including the American Farm Bureau Federation, American Soybean Association, American Trade Seed Association (ASTA), and DuPont-Pioneer. In their public comments, stakeholders articulated the

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[17]Monsanto stakeholder letter, (December 15, 2009). Available http://accordingtomonsanto.files.wordpress.com/2009/12/stakeholder-letter00011.pdf.

[18] Monsanto "Roundup Ready Soybean Patent Expiration," (undated). Available http://www.monsanto.com/newsviews/Pages/roundup-ready-patent-expiration.aspx.

broader concerns associated with the need for a structured transition to generic competition and ensuring a path to market. In response, the patent-holder indicated an openness to developing new stacked trait combinations with rival biotechnology developers, noting that the company had "enabled multiple channels for on-patent development and commercialization with the RR® event" for all stacks except multiple glyphosate-tolerant traits.[19] Monsanto also noted that the Food and Agriculture section of the Biotechnology Industry Organization (BIO) was tasked with coordinating the transition process.

While these moves appear to be in the right direction, the process thus far lacks the critical elements necessary to ensure that the goal of generic competition is reached. As it is currently proceeding, the transition to generic competition may be hampered by two weaknesses. First, as a matter of general policy, the process by which rivals gain access to on-patent stacking rights and on-patent and post-patent data should not be based on informal assurances by a patent-holder. Such assurances or commitments are difficult to enforce and do not facilitate the certainty and timing necessary to produce a clear path to market. Incentives to stymie generic competition in its infancy are too strong, particularly when the successor to RR® is in the market and actively promoted by the patent-holder.

Second, both BIO and ASTA have formed working groups to address generic competition issues. While some progress appears to have been made on drafting *pro forma* terms of IP access, those terms are still being debated. These working groups may yield a productive outcome over the long haul. But it is likely to be a contentious and cumbersome process, complicated by multiple

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[19]Letter from Jerry Steiner to Bob Stallman (February 26, 2010), at p. 2. Available http://www.monsanto.com/newsviews/Documents/afbf_letter_02-26-10.pdf. *See also* letter from James P. Tobin to stakeholders (July 8, 2010). Available http://www.monsanto.com/newsviews/Pages/Roundup-Ready-Soybean-Post-Patent-Commitment-Extended-through-2021.aspx.

stakeholder views and agendas that will not produce results fast enough or transparent enough to ensure that a generic trait makes it to market at the time of patent expiration.

VII. Policy Priorities

The issues described above have previously been encountered in promoting generic competition for pharmaceuticals and agrochemicals. As noted earlier, however, the challenge in transgenic seed, however, is complicated by a number of key factors, including: a dominant firm in the markets for genetic traits, the availability of a successor technology, and the necessity of stacking traits to produce commercially viable seed products. Addressing these concerns will require a transparent and enforceable approach, and the speed with which to implement it. At least two major policy implications are clear from the foregoing discussion.

- *An aggressive, independent industry initiative, backstopped by a legislative agenda, is needed to develop transparent and enforceable terms and conditions governing the IP "access" issues necessary to perform R&D with generic* RR®

As noted earlier, the current working industry working groups will need to proceed aggressively, quickly, and efficiently to produce transition process to ensure the certainty needed by market participants to make the investments in new R&D and deliver the benefits of generic competition to growers and consumers. This is a tall order, particularly when industry groups must also resolve stakeholder differences. A backstop legislative agenda might therefore be necessary in the case of transgenic seed. Experience in other areas illustrates the role of statutory provisions governing on-patent access.

For example, the Hatch-Waxman Act makes provisions to facilitate generic pharmaceutical entry by creating a window in which there is a hiatus on patent-infringement claims relating to development associated with regulatory approvals toward the end of the patent period, in exchange

for a short extension of the patent. Under the provision, regulatory agencies can use the approval data from the patent-holder to expedite approval of generic products after patent expiration. Similarly, for agrochemicals, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), contains a process for binding arbitration between two companies regarding compensation for data if the two companies cannot reach a private agreement.

To be sure, the Hatch-Waxman and FIFRA models may not be an exact fit for a legislative approach for promoting generic competition in transgenic seed. Any legislative approach would need to draw upon the specifics of the transgenic seed markets and technology, while considering the general experience in pharmaceuticals and agrochemicals. Moreover, implementing a legislative agenda may not be feasible given the already cramped time frame. Nonetheless, the process would benefit from movement in this direction, beginning with congressional hearings that would put the ball in motion.

- *Antitrust enforcement is needed to resolve fundamental competitive issues surrounding the appropriate use of IP, versus strategic competitive use of IP that potentially harms competition and consumers.*

In view of the probability that the industry and/or Congress may not deal with generic competition in a timely way, it becomes more important to utilize antitrust enforcement. As noted earlier, merger enforcement is the major area of antitrust that has addressed the role of IP in competitive issues involving transgenic seed. Other areas of antitrust - such as anti-monopoly enforcement under Section 2 of the Sherman Act - have been less effective. The courts have opined that there is a boundary on the use of IP. For example, the U.S. Court of Appeals for the D.C. Circuit summed up the debate in the Microsoft case when, in a unanimous ruling, it stated that

"[i]ntellectual property rights do not confer a privilege to violate antitrust laws."[20] However, the courts have been less clear about defining the types of conduct that exceed the boundaries of IP protection and stray into the area of injuring competition. This is a more difficult question and is likely to be complicated by business justifications such as quality control for refusing to license, or selectively licensing, technology.

To date, nothing appears to have come of the DOJ's investigation into Monsanto's business practices. This may signal a number of things, including the reluctance of the agency to bring a Section 2 case in the arena where IP meets antitrust. However, overcoming the hurdles associated with bringing a Section 2 case involving transgenic seed would allow antitrust enforcement to play a necessary and expected role in ensuring that the dominance of a single firm in the genetic traits markets is not used to impede generic competition. Such a development would address two problems.

First, an antitrust remedy for monopolization would address the IP access issues described in this White Paper that are central to promoting generic competition. Second, a strong Section 2 case would provide market participants with important and needed clarification regarding the intersection of antitrust and IP law. Patent-holders would gain the predictability of how their on-patent conduct will be judged. Rivals and consumers would better understand the parameters on IP licensing and access, providing needed certainty that is essential to making investment and consumption decision.

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[20] *U.S. v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir. 2001) (quoting *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325 (Fed. Cir. 2000)).