REGULATORY COMPETITIVE SHELTERS AS INCENTIVES FOR INNOVATION IN AGROBIOTECH

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2015 MICH. ST. L. REV. 553

Regulatory competitive shelters[1] (RCSs; a.k.a. regulatory exclusivities) are well known in the pharmaceutical industry as an effective way to incentivize technological innovation while creating passageways for follow-on (generic) entry into the market in the regulated products.[2] RCSs, however, have played a less significant role in the innovation economy of other areas of technology, including agricultural biotechnologies (agrobiotech).[3]

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1. RCSs "are competitive advantages resulting from statutory bars on regulatory action where such action is otherwise mandated [in legislation] and would have taken place but for the triggering of the bar." *See* Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. (forthcoming 2015) (manuscript at 10) (on file with author). In other words, the "agency's non-action," which is dictated by the statutory bar, "creates an impediment to competition in [the] market" or in a product or activity that is regulated by that agency, "thereby effectively sheltering the beneficiary of the earlier regulatory action from potential competition" and resulting in exclusivity in the regulated market or product. *Id*. (manuscript at 10-11).

2. *See id*. (manuscript at 10-14, 92 n.222).

3. The term "agrobiotech" as used in this Article pertains to and includes the following classes of technologies: (a) genetically engineered (GE) and bred varietals of food and animal-feed crops (including algae), e.g., soybeans and hybrid corn; (b) GE and bred varietals of food animals, e.g., GE salmon and black angus cattle; (c) cells bred in cultures and meant for consumption as food, e.g., yeast and *in vitro* meat; (d) GE and bred varietals of non-food crops, e.g., cotton; (e) GE and bred varietals of non-food animals, e.g., horses, donkeys, and sheep (when grown for wool); (f) pesticides of all sorts, including plant-incorporated protectants (PIPs); (g) food products that are produced from and are a byproduct of GE and bred varietals of any organisms (animals, plants, and microorganisms) where the organism itself is not consumed, e.g., milk, honey, eggs of all sorts (including

Currently in the United States, there are eight statutory regimes that create fourteen specific RCSs (there used to be fifteen, but one of the regimes is no longer applicable since 1984).[4] Most of these RCS frameworks are in the context of food and drug law and are administered by the Food and Drug Administration (FDA), where they work in conjunction with patents. However, interestingly, the first RCS regime ever created was established in 1978 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in the technological context of agrobiotech.[5] Administered by the Environmental Protection Agency (EPA),[6] the FIFRA RCS regime is probably one of the most thoughtfully crafted RCS regimes to date.

Under the FIFRA RCS regime, pesticide products approved by the EPA stand to benefit from a ten-year data-exclusivity period.[7] In other words, under FIFRA, upon determination by the EPA that a pesticide product is sufficiently safe, based on data submitted by the applicant, any party seeking EPA approval for its own follow-on, generic version of the same pesticide product would be unable to rely on the safety data submitted by the original applicant for a period of ten years. This creates what is known as "'data exclusivity,'" a period during which the submitter of the data is able to exclusively benefit from the data submitted to the agency, wherein the data is withheld from and cannot be relied upon (not even by reference[8]) by third parties.[9] Uniquely, RCSs created under FIFRA can be waived at will by their beneficiaries,[10] which effectively creates the ability to

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caviar), and swallow nests (in Chinese cuisine); and (h) fertilizers and nitrogen-fixing bacteria (for use with legumes).

4. *See* Heled, *supra* note 1 (manuscript at 49-53 tbl.3).

5. *See* Act of Sept. 30, 1978, Pub. L. No. 95-396, 92 Stat. 819; Heled, *supra* note 1 (manuscript at 61).

6. *See* Heled, *supra* note 1 (manuscript at 50, 54, 57-58).

7. *See* 7 U.S.C. § 136a(c)(1)(F)(i) (2012).

8. Notably, it has been argued that, at least in some cases, the proprietary nature of such data submitted to administrative agencies cannot be divulged to third parties. This, however, does not preclude the agency from indirectly relying on the data "by reference" in evaluating applications for marketing approval of follow-on products without actually disclosing it to the follow-on applicant. *See* Heled, *supra* note 1 (manuscript at 18-23) (discussing property interests in data submitted to administrative agencies in connection with and as part of RCS regimes).

9. *See id*. (manuscript 31-32) (quoting Donna M. Gitter, *Innovators and Imitators: An Analysis of Proposed Legislation Implementing an Abbreviated Approval Pathway for Follow-On Biologics in the United States*, 35 FLA. ST. U. L. REV. 555, 572 n.108 (2008)).

10. *See* 7 U.S.C. § 136a(c)(1)(F)(iii).

monetize on such data exclusivities or "trade" in them with potential competitors seeking to enter the market.

The ten years of data exclusivity under the FIFRA regime are then followed by a five-year mandatory-compensation period, during which the generic applicant must make an offer to compensate the original submitter of the data.[11] If they disagree on the amount of compensation, FIFRA further establishes a mechanism to resolve the dispute.[12] The ten-year period is also extendable by up to three periods of one year each for adding three "minor uses" to the pesticide's label.[13] According to the EPA's Pesticide Product Information System (PPIS), to date, the EPA has registered over 95,000 pesticide products under FIFRA.[14]

The other RCSs relevant to agrobiotech all apply to genetically engineered (GE) animals[15] and are the result of an interesting and broad construction by the FDA of the term "animal drug" under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA).[16] Under that construction, the FDA views genetic modifications entered into animals as a "new animal drug,"[17] requiring approval for safety and efficacy.[18] By requiring such approval, the FDA, essentially, restricts the use of the resulting genetically modified animals and, if the genetic trait is inheritable, its

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11. *Id*.

12. *See id*.

13. *Id*. § 136a(c)(1)(F)(ii). Such extensions make it possible for the original developer to further receive three years in total for nine additional "minor uses." *Id*.

14. *Pesticide Product Information System (PPIS)*, U.S. ENVTL. PROTECTION AGENCY, http://www.epa.gov/opp00001/PPISdata/ (last visited Mar. 17, 2015).

15. According to the FDA, "GE animal can refer to both animals with heritable r[ecombinant]DNA constructs and animals with non-heritable rDNA constructs (e.g., those modifications intended to be used as gene therapy)." FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS 3 (2011), *available at* http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm113903.pdf.

16. *See* Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988) (codified as amended in scattered sections of 21 U.S.C.).

17. 21 U.S.C. § 321(v) (2012) (internal quotation marks omitted).

18. *See* FOOD & DRUG ADMIN., *supra* note 15, at 6 ("The r[ecombinant]DNA construct in a GE animal that is intended to affect the structure or function of the body of the GE animal, regardless of the intended use of products that may be produced by the GE animal, meets the [Federal Food, Drug and Cosmetic Act] drug definition. A non-heritable r[ecombinant]DNA construct that is intended to affect the structure or function of a GE animal or to cure, mitigate, or treat a disease in the animal also meets the drug definition.").

progeny.[19] From an RCS perspective, this means that a genetic modification of an animal approved as an "animal drug" is subject to the GADPTRA RCS regime, which, in a nutshell, entails a five-year market and data exclusivity for new animal drugs, three-year market and data exclusivity for new uses of existing products, and a 180-day exclusivity for a first generic applicant to challenge patents covering an animal drug.[20]

The FDA's policy that views genetic modifications made to an animal as an "animal drug" is relatively new—only since 2011[21]—and so we are still not at the point where we may see how it plays out with relation to potential generic applicants trying to enter the market with their own versions of previously approved genetically modified animals. It would be interesting to see, however, to what extent, if any, the GADPTRA RCSs would provide meaningful protection to varietals of GE animals.

Another interesting question raised by the FDA's policy treating the genetic modification of animals as "animal drugs" under GADPTRA is why stop at animals? Namely, why does the FDA view only animals (and not even *all* animals) as a necessary subject of its regulation, rather than *any* organism?! Is there anything special in animals as such over plants and bacteria in this context? And if so, what is it?[22] Could it be that the FDA's decision to regulate genetically modified organisms (and, again, only just some of them) is rooted in public pressure and anxiety over genetically modified

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19. *See id*.

20. Notably, these patents are listed in an FDA-run listing known as the Green Book. *See Approved Animal Drug Products (Green Book)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM2006464 (last visited Mar. 17, 2015).

21. *See* FOOD & DRUG ADMIN., *supra* note 15, at 1.

22. The FDA divides GE animals into six classes based on the purpose of the genetic modification:

> (1) to enhance production or food quality traits (e.g., pigs with less environmentally deleterious wastes, faster growing fish); (2) to improve animal health (e.g., disease resistance); (3) to produce products intended for human therapeutic use (e.g., pharmaceutical products or tissues for transplantation; these GE animals are sometimes referred to as "biopharm" animals); (4) to enrich or enhance the animals' interactions with humans (e.g., hypo-allergenic pets); (5) to develop animal models for human diseases (e.g., pigs as models for cardiovascular diseases); and (6) to produce industrial or consumer products (e.g., fibers for multiple uses).

See FOOD & DRUG ADMIN., *supra* note 15, at 4. At least five of these six purpose classes (1, 2, 3, 4, and 6) are, arguably, also applicable to non-animal organisms such as plants and bacteria.

organisms rather than science? Regardless of the answers to these questions, the FDA's move toward application of GADPTRA to genetically modified animals may provide additional incentives for technological innovation in the area of genetically modified animals, which may be a first step in the "Hatch–Waxmanizing"[23] of the area of agrobiotech.

23. The idea of "Hatch-Waxmanizing" the area of agrobiotech is discussed in Jennifer Carter-Johnson's article in this volume. *See generally* Jennifer Carter-Johnson, *Defining Limited to the Application of the Statutory Experimental Use Exception Within the Agricultural Biotechnology Industry*, 2015 MICH. ST. L. REV. 509.