INSIDE

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IN FUTURE ISSUES

- Farm Bill

Antibiotics and resistant bacteria

The widespread use of antimicrobial drugs accompanies our country's production of livestock. Sometimes, producers use these drugs at low levels for therapeutic disease treatments.[1] In other situations, low levels of antimicrobial drugs improve feed efficiency and increase daily rates of weight gain.[2] These drugs may also enhance carcass quality in cattle. The benefits accruing from the use of antimicrobial drugs accord producers significant financial incentives to administer them to their animals.

Opposed to these advantages are risks that bacterial will develop antimicrobial resistance. Resistance means the bacteria can block the killing effects of a particular drug so that we need another method of control. This generally involves the development of a new antibiotic, an expensive and costly process. Experts estimate that we spend $30 billion per year due to the cumulative effects of antimicrobial resistance.[3]

Scientists have estimated that about 26.6 million pounds of antibiotics are administered to domestic livestock each year.[4] This compares with three million pounds used for humans. Less than 8% of the antibiotics administered to animals are to treat active infections.[5] The remaining quantities of drugs are to enhance animal growth and producers' profits. About 70% of the large swine operations in the United States administer antibiotics via injection, feed, water, and orally; for cattle, 57% receive antibiotics.[6]

Drugs administered to livestock help control animal infections that they may transfer to humans.[7] Given the ability of bacteria to develop antimicrobial resistance, concern exists whether the widespread use of antibiotics in animals exacerbates the rising incidence in human pathogens. Experts believe that resistant strains of organisms cause illness or disease in humans. *Salmonella*, *Campylobacter*, and *E. coli* are linked to the use of antibiotics in animals.[8] To respond to antimicrobial resistance, scientists and governments are proposing to limit antibiotics approved for use in livestock production.

Several European countries have taken action to preclude the use of antimicrobial drugs in feed to enhance growth or feed efficiency.[9] The American Medical Association passed a resolution in 2001 opposing nontherapeutic uses of antibiotics in agriculture.[10] Federal agencies have considered further regulation of antibiotics used in agriculture. The Department of Health and Human Services believes that

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Seventh Circuit stays USDA's immediate and indefinite suspension of PACA dealer's license

The Seventh Circuit has stayed, pending plenary adjudication of the dispute by the court, the USDA's immediate and indefinite suspension of a license held by a dealer under the Perishable Agricultural Commodities Act (PACA), 7 U.S.C. §§ 499a-499s. *Finer Foods, Inc. v. United States Department of Agriculture*, 274 F.3d 1137, 1141 (7th Cir. 2001). Rejecting the USDA's claim that it lacked subject matter jurisdiction as "frivolous," the court ruled that the USDA's suspension order was both an "order" as that term is defined in section 551(6) the Administrative Procedure Act (APA), 5 U.S.C. § 551(6), and a "final order" for purposes of section 2344 of the Hobbs Administrative Orders Review Act, 28 U.S.C. §§ 2341-2351. *Id*. at 1138-39. In granting petitioner Finer Food's request for a stay of the suspension order, which was unaccompanied by an opportunity for a hearing and purported to be indefinite in duration, the court ruled that Finer Foods "was entitled to some hearing before its license was yanked." *Id*. at 1141 (citations omitted). In part, the court grounded

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the scientific evidence justifies taking steps to decrease use of antibiotics in agriculture while the USDA believes more research is needed before implementing new regulations reducing the use of antibiotics.[11]

Placing the problem of antimicrobial resistance into the context of animal production, evidence suggests that the use of antibiotics increases with larger production facilities. Large swine CAFOs are three times as likely to use antibiotics in feed and water compared with small operations.[12] large cattle operations are twice as likely to administer antibiotics to animals in their feed and water. 13 Thus, many believe that concentrations of animals are exacerbating the problem of antimicrobial resistance.

— Terence J. Centner, Professor, The University of Georgia

[1] Kenneth H. Matthews, Jr., *Antimicrobial Resistance and Veterinary Costs in U.S. Livestock Production* (Washington: U.S. Department of Agriculture, Economic Research Service, December, 2000).

[2] Ibid. 7.

[3] American College of Physicians-American Societiy of Internal Medicine, "Emerging Antimicrobial Resistance Facts and Figures," http://www.acponline.org/ear/index.html (viewed February 14, 2002).

[4] Jane E. Brody, "Studies Find Resistant Bacteria in Meats," *The New York Times*, A12, October 8, 2001.

[5] Id

[6] Animal and Plant Health Inspection service, *Antimicrobial Resistance Issues in Animal Agriculture* 24 (Washington: U.S. Department of Agriculture, December 1999).

[7] Id. at 17.

[8] General Accounting Office, *Food Safety: The Agricultural Use of Antibiotics and Its Implications for Human Health* 4 (Washington: GAO/RCED-99-74, April 1999).

[9] Matthews, supra note 1, at 3.

[10] Robbin Marks, *Cesspools of Shame: How Factory Farm Lagoons and Sprayfields Threaten Environmental and Public Health* (Washington: Natural Resources Defense Council and Clean Water Network, July 2001) 24.

[11] General Accounting Office, supra note 8, at 2.

[12] Animal and Plant Health Inspection Service, supra note 6, at 24.

[13] Id. at 24.

VOL. 20, NO. 3, WHOLE NO. 220 February 2002

AALA Editor.....Linda Grim McCormick
2816 C.R. 16, Alvin, TX 77511
Phone: (281) 388-0155
FAX: (281) 388-0155
E-mail: lgmccormick@teacher.esc4.com

Contributing Editors: Terence J. Centner, The University of Georgia, Athens, GA; Monica M. Clark, Fayetteville, AR; Scott Fancher, Harrison, AR; Phillip B.C. Jones, Seattle, WA.

For AALA membership information, contact Donna French Dunn, Executive Director, 4115 South Duff Avenue, Suite C, Ames, IA 50010-6600. Phone: (515) 956-4255.

Agricultural Law Update is published by the American Agricultural Law Association, Publication office: Maynard Printing, Inc., 219 New York Ave., Des Moines, IA 50313. First class postage paid at Des Moines, IA 50313.

Battles and skirmishes in the biotech patent arena

2001 saw a worldwide escalation in apprehensions about biotech patents. Gene patents appeared to have been viewed with a particularly jaundiced eye. In October, for instance, the International Bioethics Committee of the United Nations Educational, Scientific and Cultural Organization called upon UNESCO to promote the adoption of an international moratorium on the granting of gene patents until any ethical ramifications could be explored. During a *60 Minutes* show, Morley Safer warned that "chances are, your genetic structure and mine, our most private property, may well belong to someone else." Although ludicrous, this statement undoubtedly made an impression on many viewers. According to *60 Minutes*, one of the major concerns about gene patenting is that it hinders research. Yet in response to a questionnaire issued by the European Parliament, Gugerell Christian, Director of the European Patent Office, stated that, in spite of the large number of gene patents, he is not aware of a single incidence where gene patents hampered research. Still, the perception persists that patents have a chilling effect on basic research.

Agbiotech patents did not escape misgivings. In early November, the International Treaty on Plant Genetic Resources for Food and Agriculture was adopted with two abstentions (the U.S. and Japan). An objective of this treaty is to discourage patents on food crops. During the same month, the Canadian Biotechnology Advisory Committee released its interim report, which recommended the creation of a farmer's privilege within the Patent Act. A concern here is that a patent owner could have rights to seed produced in farmers' fields, an issue that US Supreme Court Justices raised during the recent oral hearing of *Pioneer Hi-Bred International Inc. v. J.E.M. AG Supply Inc.[Editor's note: This case was reported on in the January 2002 Agricultural Law Update, pp. 4-6.]*

Many found current patent law adequate for fighting or circumventing particular patents.

Waging the patent battle at the source

One popular battlefield is a patent's birthplace—the patent office. In the European Patent Office (EPO), a third party can challenge the validity of a European patent within nine months of the publication of the notice to grant the patent. An Opposition proceeding may result in the patent being upheld in an unchanged or amended form, or the Opposition Division may decide to revoke the patent. Claiming bio-piracy, the Mexican government reportedly filed a request for an Opposition last summer to halt DuPont's European patent on a maize variety called OPTIMUM HOC/HO, which the government claims originated in Mexico.

Although the US does not offer an Opposition mechanism, a third party can challenge a patent by initiating a reexamination proceeding with the US Patent and Trademark Office (USPTO). The International Center for Tropical Agriculture filed such a request for reexamination of a patent owned by Pod-ners LLC, which claims a *Phaseolus vulgaris* field bean. In January 2001, the USPTO published its intent to reconsider the patent. In yet another case of alleged biopiracy, India's Agricultural and Processed Food Exports Authority challenged three US patent claims held by RiceTech, Inc. (Alvin, TX). In August, following reexamination, the USPTO reduced the original twenty claims to five.

When reexamination fails, a party can turn to the courts. In 1999, Brassica Protection Products LLC (Baltimore, MD) and Johns Hopkins University sued Sproutman, Inc. (Upper Black Eddy, PA) for infringement of patents relating to the production and consumption of cruciferous seed sprouts. While the litigation was proceeding, Sproutman initiated a reexamination proceeding, and the USPTO ultimately reaffirmed the validity of the claims. Last summer, however, the court heard arguments in the infringement action and decided that the patents are invalid due to a lack of novelty.

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this ruling on its observation that PACA § 499m(a) limits the Secretary's suspension authority by providing that "the Secretary may, after thirty days' notice and an opportunity for a hearing, ... suspend the license of the offender for a period not to exceed ninety days." *Id*. at 1140-41.

The suspension order was apparently precipitated by the failure of Finer Foods, a PACA licensed dealer, to submit for inspection certain records that its Fruit and Vegetables Program Branch had requested. The PACA grants to the Secretary the right to inspect certain "accounts, records, and memoranda" of PACA licensees and "any lot of any perishable agricultural commodity" covered by the PACA. 7 U.S.C. § 499m(a). If a licensee refuses to permit an inspection of "accounts, records, and memoranda," PACA § 499m(a) permits the Secretary to "publish the facts and circumstances and/or, by order, suspend the license of the offender until permission to make such inspection is given." If the refusal pertains to "any lot of any perishable agricultural commodity" under the ownership or control of a licensee, the Secretary "may after thirty days notice and an opportunity for a hearing, publish the facts and circumstances and/or, by order, suspend the license of the offender for a period not to exceed ninety days." 7 U.S.C. § 499m(a).

Orders issued by the Secretary under the PACA are subject to judicial review under the Hobbs Act. *See* 28 U.S.C. § 2342(2). In response to Finer Foods' invocation of the Hobbs Act by its petition to stay the suspension order pending the court's review, the USDA challenged the court's jurisdiction on two grounds. First, the USDA argued that the court lacked personal jurisdiction over it because the court's clerk had served the petition by fax, and it had not received the service by mail that is required by section 2344 of the Hobbs Act. The court rejected this argument, noting that the clerk had timely served the petition by fax and mail and that the latter service apparently had been delayed by the security measures taken after the terrorist attacks on September 11. *Finer Foods,* 274 F.3d at 1138-39. The court opined that while the USDA was free to notify it of any objections to electronic notification, such notice does not "deprive parties such as Finer Foods—which lack influence over either the postal system or the Clerk's office—of their judicial remedy." *Id.* at 1139.

The court also summarily rejected the USDA's contention that the court lacked subject matter jurisdiction because the suspension order was not a "final order" as required for subject matter jurisdiction under the Hobbs Act. *See* 28 U.S.C. § 2344. The court reasoned that the suspension order was "final," "not only because of the ongoing effect, but also because no further administrative review is available." *Finer Foods,* 274 F.3d at 1139 (citation omitted). The court observed that PACA § 499m(a) allows the USDA, "by order," to suspend licenses until requested information is provided and that APA § 551(6) defines an administrative "order" as a final decision. *Id.* at 1139. Because the suspension order was perpetual and the USDA had not offered a hearing to Finer Foods, reasoned the court, the order was "final" and subject to judicial review.

Having concluded that it had jurisdiction, the court turned to the merits of the petition. Although PACA § 499m(a) authorizes the USDA to suspend a PACA license either with or without a hearing and until inspection is granted or for a period not exceeding ninety days, depending on the subject matter of the requested inspection, the court did not expressly acknowledge these distinctions. Instead, the court invoked only the portion of section 449m(a) that appears, on its face, to apply when there has been a refusal to inspect "any lot of perishable agricultural commodity" covered by PACA. It characterized the USDA's position that Finer Foods was not entitled to a hearing until the USDA commenced a disciplinary proceeding against Finer Foods as a claim to "an unfettered right to shut down any middleman in the produce business that does not knuckle under to an administrative request for records, no matter how burdensome the compliance and no matter how slight the government interest in conducting the investigation." *Id*. at 1140-41. The court described the USDA's actions as "discovery run riot" and concluded that "Finer Foods was entitled to some hearing before its license was yanked." *Id.* at 1141. It stayed the suspension pending its plenary adjudication of the dispute. *Id*.

—*Monica M. Clark, NCALRI, Graduate Fellow*

This article is based upon work supported by the U.S. Department of Agriculture, under Agreement No. 59-8201-9-115. Any opinions, findings, conclusions, or recommendations expressed in this article are those of the author and do not necessarily reflect the view of the U.S. Department of Agriculture.

Battles/Cont. from page 2

Prior art: offensive and defensive tactics

These strategies of patent attack relied upon prior art for ammunition. One policy underlying patent law is that the patent grant should not remove something from the public domain, and for this reason, a claimed invention must be novel. That is, an invention must differ from the prior art, which is the sum of publicly available information. In addition, a patent should not issue for a claimed invention that would have been an obvious variation of something in the prior art. A recently created dot-com called "BountyQuest" takes advantage of the patent-busting power of prior art by allowing individuals or companies to challenge a patent for a $2,500 fee plus a cash prize of $10,000 or more. The prize goes to the person who can uncover prior art that could invalidate the patent. As an example, a $20,000 bounty was posted for a Monsanto patent with claims to DNA encoding enzymes that can render plants tolerant to glyphosate herbicide. This bounty apparently closed without anyone collecting. However, a German graduate student won a $10,000 bounty for his submission of documents on an Incyte Genomics, Inc. (Palo Alto, CA) patent that covered a relational database system for storing and manipulating large amounts of genetic information.

Instead of finding prior art, a preemptive strike can be initiated by creating prior art. Meeting for the first time in 2001, a special body of the World Intellectual Property Organization (the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore) considered the topic of a more effective integration of traditional knowledge documentation into searchable prior art. Meanwhile, India is developing a digital library of its traditional knowledge and will provide access to US and European patent offices. Individuals who wish to publicly disclose their invention as a defensive publication strategy can use the services of IP.com, which publishes invention disclosures on the Web.

Taking aim at patents on diagnostics

In May, Myriad Genetics, Inc. (Salt Lake City, UT) announced that it had received eight patents in the US and abroad, covering the *BRCA1* and *BRCA2* breast and ovarian cancer genes and their use in the development of therapeutic and predictive medicine products. After obtaining their Canadian patent, Myriad reportedly demanded the Canadian provinces route tests involving the patented genes to the company's laboratory or to designated licensees. In response to the higher costs, the British Columbia health ministry halted testing in August. Ontario

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FCIC's Standard Reinsurance Agreement

By Scott Fancher

Crop insurance is becoming increasingly popular as a risk management tool for farmers.[1] The Agricultural Risk Protection Act of 2000 (ARPA) is evidence that it also enjoys broad support in Congress.[2] ARPA significantly expanded the scope of the crop insurance program.[3] It also made participation more attractive and likely by substantially increasing the share of the premiums paid by the government.[4] It follows that there now exists an increased opportunity for disputes involving federal crop insurance.

Crop insurance can be very confusing for anyone unfamiliar with its mechanics. This is due, at least in part, to the federal government's involvement in its promotion and delivery.[5] That involvement imposes obligations on both the government and the private crop insurance providers. Certain of these obligations are not immediately obvious from contracts for crop insurance, even though they may have implications for the outcome of disputes on those contracts.[6] Consequently, both farmers and their attorneys can benefit from a fundamental understanding of the roles and responsibilities of the different stakeholders in our federal crop insurance system. This writing addresses the relationship between two of those stakeholders: the Federal Crop Insurance Corporation (FCIC) and the private insurance companies that it authorizes to sell and service approved policies.

Background

The Federal Crop Insurance Act (FCIA) created the FCIC as a wholly owned government corporation within USDA responsible for delivery of federal multiple peril crop insurance.[7] It is managed by a ten-member Board of Directors subject to general supervision by the Secretary of Agriculture.[8] FCIC programs are administered by the Risk Management Agency (RMA), and the RMA Administrator is the designated Manager of FCIC.[9] Federal crop insurance is currently sold and serviced by private companies under reinsurance agreements with FCIC.[10]

The Standard Reinsurance Agreement

The relationship between the FCIC and the companies providing federally subsidized crop insurance is governed by a Standard Reinsurance Agreement (SRA).[11] FCIC reinsurance agreements were first authorized in 1947 but saw little use until the 1980 amendments to the FCIA.[12] Reinsurance reduces the financial risks assumed by an insurer because the risks of catastrophic losses are spread among a pool of insurers.[13] Reinsurance arrangements are often favored by insurers because they reduce their reserve requirements and enhance their profitability.[14]

The SRA incorporates the FCIA and FCIC regulations by reference.[15] Under the SRA, the FCIC reinsures approved policies written by private insurance companies.[16] FCIC obligates itself to pay a predetermined portion of the policy premium as set out in the FCIA.[17] FCIC also agrees to pay losses on policies where the reinsured company is unable to pay because of orders or directives from a regulatory agency or court with competent jurisdiction.[18] FCIC's liability, however, is not limitless. FCIC can refuse to accept additional policies from the reinsured companies with written notice.[19] More importantly, any liability assumed by FCIC under the terms of the SRA is subject to adequate appropriations.[20]

The SRA obligates the reinsured companies to sell and service federal crop insurance according to FCIC procedures.[21] Reinsured companies must file a plan with the FCIC that designates the counties and states where it proposes to operate.[22] Once the plan of operations is approved by FCIC, a reinsured company must offer its insurance products to all eligible producers in those areas.[23] A company is also required to offer catastrophic risk protection (CAT) and traditional buy-up insurance in its approved area of operations where those products are not offered by local USDA offices.[24] The SRA further requires that reinsured companies use only those forms and loss adjustment procedures that are approved by the FCIC.[25] Reinsured policies can only be sold through licensed agents or brokers that are FCIC certified.[26]

FCIC's SRA has evolved over time to reflect and incorporate various amendments to the FCIA.[27] The current version of the SRA was authorized in 1998 and implemented in 1999.[28] The SRA may change again soon because ARPA specifically authorized FCIC to change its terms once between 2001 and 2005.[29] Under the existing SRA, FCIC provides both proportional and non-proportional reinsurance.[30] Insurers are allowed to commercially reinsure any retained portion of their liability not ceded to FCIC, provided they fully disclose the details in their plan of operations.[31]

Proportional reinsurance

Under its proportional reinsurance provisions, private insurers may designate eligible contracts into Assigned Risk, Developmental, or Commercial funds.[32] Any eligible contracts, including CAT and revenue policies, can be designated to the Assigned Risk fund, but maximum cession rates per state are imposed.[33] All contracts designated into the Assigned Risk fund are combined in a single fund within each State.[34] Except in limited circumstances, the insurer must retain 20 percent of the net book premium and associated liability for contracts designated into the Assigned Risk fund.[35] Any liability not retained is ceded to FCIC in return for a corresponding percentage of the premiums.[36]

There are three Developmental funds: fund C for CAT policies, fund R for revenue policies, and fund B for all other policies.[37] Insurers must retain at least 35 percent of the net book premium and liability for contracts designated into these funds, but may increase that amount in 5 percent increments for any State, provided they specify that intention in their plan of operations.[38] Insurers are allowed to vary retention percentages among the three Developmental funds within a State.[39] As with the Assigned Risk fund, the non-retained portion of the risk and premium is ceded to FCIC.[40]

The options for insurers with respect to the Commercial fund(s) are similar to those for the Developmental funds. A reinsured company must retain at least 50 percent of the net book premium and liability on contracts designated to these funds.[41] The retention percentages can differ among the three funds (CAT, Revenue, Other) and can be greater than 50 percent if specified in the reinsured companies' plan of operations.[42] Any contracts that are not designated into the Assigned Risk or Developmental funds default into the appropriate Commercial fund.[43] As with the non-retained portion of the other funds, liability for loss and a corresponding percentage of the associated premium are ceded to FCIC.[44]

Companies must retain a minimum of 35 percent of their entire book of crop insurance business under the current SRA unless: 1) more than 50 percent of their book of business is in the assigned risk fund; or 2) all of their contracts are designated into the assigned risk or developmental funds.[45] Where either condition is satisfied, the minimum retention requirement is lowered to 22.5 percent.[46] If an insurer does not meet the overall retention requirement, FCIC in-

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Scott Fancher, LL.M. in Agricultural Law candidate, is in solo practice in Harrison, Arkansas. He is a former FSA County Executive Director and certified crop insurance critical loss adjuster.

creases their minimum 20 percent retention requirement for the Assigned Risk fund on a pro-rata basis sufficient to bring them into compliance.[47]

Stop-loss reinsurance

The non-proportional reinsurance provided under the SRA limits the liability exposure for insurers on their retained book of business.[48] The share of loss on an insurer's retained book of business assumed by FCIC varies by fund and depends on the insurer's loss ratio.[49] Loss ratios are calculated separately for each fund and state. FCIC uses a graduated system under which an insurer is responsible for decreasing percentages of ultimate net losses as its loss ratios increase.[50] For example, an insurer with a loss ratio of 150 percent on the portion of its revenue plans not ceded to FCIC and designated to the commercial fund would be responsible for 57 percent of the ultimate net loss.[51] However, if that same insurer had a 200 percent loss ratio, then it would be responsible for 57 percent of the first 160 percent of its losses and for 43 percent of the remaining loss.[52] FCIC assumes 100 percent of the liability for losses in excess of 500 percent.[53]

Underwriting gains and losses

The SRA also specifies how much of any underwriting gains an insurer gets to keep. This amount is calculated on a graduated basis with the percentage of gains retained decreasing as loss experience improves.[54] For example, an insurer with a loss ratio of greater than or equal to 65 percent but less than 100 percent, gets to retain 94 percent of the gain from revenue plans designated into the commercial fund.[55] Where the loss ratio is greater than or equal to 50 percent but less than 65 percent, the insurer gets to keep 70 percent of the gain from contracts similarly designated.[56] And where the loss ratio is less than 50 percent for revenue plans designated into the commercial fund, the insurer retains 11 percent of the gain.[57]

Underwriting gains and losses for each fund are calculated separately by state and then totaled for all states to determine an insurer's net operating gain or loss for annual settlement purposes.[58] At annual settlement, FCIC will retain 60 percent of any net gains exceeding 17.5 percent in a Reinsurance account.[59] Conversely, FCIC will charge an insurer's Reinsurance account the amount necessary to realize a gain of 17.5 percent where it has a loss or a net gain of less than 17.5 percent.[60]

Annual settlement funds maintained in the Reinsurance account are normally held for two years before being returned to the insurer on a first in— first out basis.[61] The settlement procedures at termination or non-renewal of the SRA differ depending upon which party cancels. If the insurer cancels, it is entitled to 50 percent of its Reinsurance account balance at the annual settlement date, with the balance due one year later.[62] Where FCIC cancels, the entire account balance is payable to the insured one year after the first annual settlement following cancellation.[63]

Risk subsidy, administrative and overhead expenses, and loss adjustment

The SRA provides that FCIC will subsidize crop insurance premiums as authorized by Congress.[64] These subsidy amounts have increased steadily over time and now FCIC pays the lion's share of premiums on most policies.[65] The SRA further provides that FCIC will pay an Administrative and Operating (A&O) expense subsidy to the reinsured company for certain policies.[66]

The amount of A&O subsidy is a function of the type of policy underwritten and its associated premium.[67] Under the current SRA, the reinsured company receives an A&O subsidy equal to 22.7 percent of the net book premium for Group Risk Protection (GRP) policies.[68] Reinsured companies receive 21.1 percent of the net book premium for eligible revenue insurance policies keyed to the higher of market price at planting or harvest and 24.5 percent for those keyed only to market price at planting.[69] The reinsured company receives 24.5 percent of the net book premium on all other policies except CAT.[70] There is no A&O subsidy for CAT policies;[71] however, the reinsured companies do receive loss adjustment expenses based on net book premium for eligible CAT contracts.[72]

The SRA requires the reinsured companies to remit any administrative fees collected from policyholders.[73] It also requires the reinsured companies to disclose the amount of risk (premium) and A&O subsidy borne by FCIC to the policyholders.[74] FCIC will reduce A&O subsidies where the reinsured company does not provide and process all the necessary data by an agreed upon transaction cut-off date.[75]

General provisions

Section V of the SRA contains the general provisions applicable to the reinsurance arrangement between FCIC and the private insurance companies. It imposes, *inter alia*, record keeping and reporting requirements witih which the reinsured company must comply. It also sets out the provisions for corrective action, including suspension and termination, where a review establishes that the company is not complying with the terms of the SRA.[76] If the reinsured company is otherwise in compliance, the SRA is automatically renewed July 1 of each following year, unless FCIC provides notice at least six months in advance in writing that the contract will not be renewed.[77] The general provisions further provide that FCIC is not responsible for the errors or omissions of the reinsured's sales agents or loss adjusters.[78]

The reinsured companies can challenge any "actions, finding, or decision of FCIC" arising under the SRA.[79] The applicable procedure is different depending upon the nature of the determination being challenged. For non-compliance issues, the company must request review by the Deputy Administrator of Insurance Services.[80] By contrast, the Compliance Field Offices allow the reinsured company to respond to an initial determination before issuing a final determination.[81] If the company disagrees with a final determination, it may request a final administrative determination from the Deputy Administrator of Compliance.[82]

Irrespective of the nature of the dispute, the reinsured company must submit a written request for review within 45 days of receipt of the disputed determination.[83] The SRA requires FCIC to issue a "fully documented" decision within 90 days after receiving notice of the dispute.[84] If FCIC cannot meet the 90 day deadline, then it must notify the reinsured company within that 90 days why it cannot and when its decision will be made.[85] Generally, final administrative determinations by the responsible Deputy Administrator may be further appealed to the Board of Contract Appeals.[86] Certain FCIC determinations, however, are final and may not be further appealed by the reinsured company.[87] Final administrative determinations by FCIC must be appealed in writing to USDA's Board of Contract Appeals within 90 days.[88] Reinsured companies may seek judicial review of the Board's findings in federal district court.[89]

The current landscape

There are considerably fewer companies with reinsurance agreements in place with FCIC now than there were twenty years ago.[90] It is notable because the volume of business has increased dramatically during that same period.[91] In the mid 1980's, over fifty companies contracted with FCIC to deliver federal crop insurance.[92] However, by 1997, only sixteen companies had reinsurance agreements with FCIC.[93] This decline may be partly explained by mergers and acquisitions within the insurance industry in general.[94] It should be understood that many crop insurance policies are sold and serviced by managing general agents (MGA's) for the holders, rather than by signatories themselves.[95] Companies using MGAs must fully disclose that fact in their annual plan of operations and certify to their compliance with certain laws

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and regulations.[96]

Crop insurance is experiencing the same sort of concentration common to other agricultural sectors in recent years. Farm Bureau, through its interlocking Boards of Directors, reportedly owns or controls one-third of the fourteen companies that entered into the 1999 SRA with FCIC.[97] The exact relationship of the stakeholders in federal crop insurance is hard to determine because of prohibitions against revealing corporate business strategies.[98]

The stakes in crop insurance are enormous. It is a huge industry generating billions of dollars in revenue.[99] The relatively few corporate players are well organized and have a powerful and influential national lobby.[100] The legion of sales agents representing the reinsured companies at the state and local levels compliment and increase that influence considerably.[101] This may help explain why, despite a litany of failure and criticism, crop insurance has emerged as the dominant policy element of our farm safety net.[102]

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[1] Authors note: As used here, "crop insurance" refers only to federally subsidized multiple peril crop insurance. Limited peril coverage, typically for fire and/or hail damage, is widely available through private insurers with no government involvement.

[2] *See* Agricultural Risk Protection Act of 2000, Pub. L. No. 106-224 §§ 101 - 173 (to be codified in scattered sections of 7 U.S.C. §§1501 - 1515).

[3] *See generally* Christopher R. Kelley, *The Agricultural Risk Protection Act of 2000: Federal Crop Insurance, the Non-Insured Crop Disaster Assistance Program, and the Domestic Commodity and Other Farm Programs*, 6 Drake J. Agric. L. 141, 159 (2001).

[4] *See id.* at 148-50.

[5] *See, e.g., Wiley v. Glickman*, No. A3-99-32, 1999 U.S. Dist. LEXIS 20278, at *35 (D.N.D. Sept. 3, 1999)(unreported decision). "[T] he court struggled along with the parties to find the law applicable to the confusing interstice between private insurance principles and federal farm policy." *Id* at n.9.

[6] *See, e.g., id.* at *40 (explaining that liability may be substituted from the insurer to the reinsurer in certain situations).

[7] *See* Federal Crop Insurance Act, ch. 30, 52 Stat. (1938) (codified at 7 U.S.C. § 1508).

[8] *See* Agricultural Risk Protection Act of 2000, Pub. L. No. 106-224, § 142 (to be codified at 7 U.S.C. § 1505(a)).

[9] *See* 7 C.F.R. § 2.44.

[10] "Reinsurance is a contractual arrangement whereby one insurer (the ceding insurer) transfers all or a portion of the risk it underwrites pursuant to a policy or group of policies to another insurer (the reinsurer)." Barry R. Ostrager & Thomas R. Newman, *Overview of Reinsurance*, 454 Prac. L. Inst./Lit. 339, 342 (citing *Colonial Am. Life Ins. Co. v. Comm'r*, 491 U.S. 244 (1989)); *See also* Barry R. Ostrager & Thomas R. Newman, Handbook On Insurance Coverage Disputes § 15.01 (9th ed. 1998).

[11] *See* 7 C.F.R §§ 400.161-.176.

[12] *See* Steffen N. Johnson, *A Regulatory 'Wasteland': Defining a Justified Role In Crop Insurance*, 72 N.D. L. Rev. 505, 512 (1996).

[13] *See generally* Barry R. Ostrager & Thomas R. Newman, *Overview of Reinsurance*, 454 Prac. L. Inst./Lit. 339, 342-43.

[14] *See id.* at 343 (citing *Corcoran v. Universal Reinsurance Corp.*, 713 F.Supp.77, 82 (S.D.N.Y. 1989)).

[15] *See* 7 C.F.R. § 400.164.

[16] *See id*

[17] *See* 7 C.F.R. § 400.166. ARPA significantly increased the subsidized share of MPCI policy premiums beginning with the 2001 reinsurance year. *See* Pub. L. No. 106-224, tit. I, sec. 101, 114 Stat. 358, 361-63 (codified as amended at 7 U.S.C. § 1508(e) (2000)).

[18] *See* 7 C.F.R. § 400.166. *See also* 1999 Standard Reinsurance Agreement (SRA)–Section V ¶ P, *available at* http://www.rma.usda.gov/tools/agents/sra99 b.html (last visited Feb. 20, 2002) which provides: "[A]ll eligible crop insurance contracts affected by such directive or order that are in force and subject to this Agreement as of the date of such inability or failure to perform will be immediately transferred to FCIC without further action of the Company by the terms of this Agreement." *Id*

[19] *See* 7 C.F.R. § 400.167.

[20] *See id.*; *See also* 1999 Standard Reinsurance Agreement (SRA)–Section V ¶ N, *available at* http://www.rma.usda.gov/tools/agents/sra99 b.html (last visited Feb. 20, 2002) which provides:

> Notwithstanding any other provision of this Agreement, FCIC's ability to sustain the Agreement depends upon the FCIC's appropriation. If FCIC's appropriation is insufficient to pay the obligations under this Agreement, and FCIC has no other source of funds for such payments, FCIC will reduce its payments to the Company on a *pro rata* basis or on such other method as determined by FCIC to be fair and equitable.

FCIC's Standard Reinsurance Agreement

Id (emphasis original).

[21] *See* C.F.R. § 400.168(a).

[22] *See* C.F.R. § 400.168(b).

[23] *See id.*

[24] *See id.* CAT indemnifies producers for yield losses in excess of 50 percent at 55 percent of the expected market price. *See* 7 U.S.C.S. § 1508(b)(2)(A)(ii). CAT premiums are paid by the government but the insured must pay an administrative fee "equal to 10 percent of the premium ... or $100.00 per crop per county, whichever is greater, as determined by the Corporation." *See id.* at (b)(5)(A).

[25] *See* 7 C.F.R. § 400.168(c).

[26] *See* 7 C.F.R. § 400.168(e).

[27] *See e.g.*, Johnson, *supra* note 12, at 517-18. "The 1999 Farm Bill mandated a revision of the [SRA] to ensure that reinsured companies would take greater responsibility for loss thereunder.... FCIC responded by revising the [SRA] to require greater risk retention by reinsured companies and to decrease the level of stop-loss insurance offered." *Id*

[28] *See* Agricultural Research, Extension, and Education Reform Act of 1998, Pub. L. No. 105-185, sec. 536, 112 Stat. 523, 594 (codified as amended in scattered sections of 7 U.S.C.) ("For each of the 1999 and subsequent reinsurance years, the Corporation shall ensure that each Standard Reinsurance Agreement between an approved insurance provider and the Corporation reflects the amendments to the Federal Crop Insurance Act (7 U.S.C. 1501 et seq.) that are made by this subtitle....").

[29] Pub. L. No. 106-224, tit. I, § 148, 114 Stat. 358, 394 (2000) ("Notwithstanding section 536 of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 1506 note; Public Law 105-185), the Federal Crop Insurance Corporation may renegotiate the Standard Reinsurance Agreement once during the 2001 through 2005 reinsurance years.").

[30] Proportional or pro-rata reinsurance refers to a contractual arrangement in which "the reinsurer agrees to indemnify the ceding insurer for a percentage of any losses from the original risk in return for a corresponding portion of the premium for the original risk." Barry R. Ostrager & Thomas R. Newman, Handbook On Insurance Coverage Disputes § 15.02 (9th ed. 1998).

[31] *See* 1999 Standard Reinsurance Agreement (SRA)–Section II ¶ E, *available at* http://www.rma.usda.gov/tools/agents/sra99 b.html (last visited Feb. 20, 2002).

[32] *See id.* ¶¶ B-C.

[33] *See id.* ¶ B.1.e.

[34] *See id.*

[35] *See id.* ¶ B.1.a.

[36] *See id.*

[37] *See* 1999 Standard Reinsurance Agreement (SRA)–Section II ¶¶ B.2.a, *available at* http://www.rma.usda.gov/tools/agents/sra99 b.html (last visited Feb. 20, 2002).

[38] *See id.* ¶ B.2.d.

[39] *See id.*

[40] *See id.*

[41] *See* 1999 Standard Reinsurance Agreement (SRA)–Section II ¶ B.3.b, *available at* http://www.rma.usda.gov/tools/agents/sra99 b.html (last visited Feb. 20, 2002).

[42] *See id.*

[43] *See id.* ¶ B.3.a.

[44] *See id.* ¶ B.3.b.

[45] *See id.* ¶ B.4.a.

[46] *See id.*

[47] *See id.* ¶ B.4.b.

[48] *See* Barry R. Ostrager & Thomas R. Newman, Handbook On Insurance Coverage Disputes § 15.02 (9th ed. 1998) (explaining that non-proportional or "Stop Loss" reinsurance is a form of "Excess of Loss" reinsurance which "indemnifies the ceding insurer, subject to specified limits, for all or a portion of loss in excess of a stated retention.").

[49] The definition section of the SRA provides: "'Retained' as applied to... book of business, means the remaining liability for ultimate net losses and the right to associated net book premiums after all reinsurance cessions to FCIC under this Agreement."

[50] *See* 1999 Standard Reinsurance Agreement (SRA)–Section II ¶ C, *available at* http://www.rma.usda.gov/tools/agents/sra99 b.html (last visited Feb. 20, 2002).

[51] *See id.* ¶ C.1.a.

[52] *See id.* ¶ C.1.b.

[53] *See id.* ¶ C.1.d.

[54] *See* 1999 Standard Reinsurance Agreement (SRA)–Section II ¶ D, *available at* http://www.rma.usda.gov/tools/agents/sra99 b.html (last visited Feb. 20, 2002).

[55] *See id.* ¶ D.1.a.

[56] *See id.* ¶ D1.b.

[57] *See id.* ¶ D.1.c.

[58] *See id.* ¶ D.1.c.1-2.

[59] *See id.* ¶ D.1.c.3.b.

[60] *See* 1999 Standard Reinsurance Agreement (SRA)–Section II ¶ D.1.c.3.c, *available at* http://www.rma.usda.gov/tools/agents/sra99 b.html (last visited Feb. 20, 2002).

[61] *See id.* ¶ D.1.c.3.d.

[62] *See id.* ¶ D.1.c.3.e.i.

[63] *See id.* ¶ D.c.3.e.ii.

[64] *See* 1999 Standard Reinsurance Agreement (SRA)–Section III ¶ A.1, *available at* http://www.rma.usda.gov/tools/agents/sra99 b.html (last visited Feb. 20, 2002).

[65] FCIC pays 100% of the CAT premium. *See* 7 U.S.C. § 1508 (e)(2)(A). Beginning with the 2001 crop year, FCIC subsidized buy-up policy premiums as follows (first number represents the percent of yield and the second the percent of the established market price insured): 50/100 = 67%; 55/100 = 64%; 60/100 = 64%; 65/100 = 59%; 70/100 = 59%; 75/100 = 55%; 80/100 = 48%; 85/100 = 38%. *See id.* §§ (e)(2)(B) - (G).

[66] *See* 1999 Standard Reinsurance Agreement (SRA)–Section III ¶ A.2., *available at* http://www.rma.usda.gov/tools/agents/sra99 b.html (last visited Feb. 20, 2002).

C*ont. on p. 7*

Crop insurance/Cont. from p.3

[67] *See id.* "A&O subsidy for eligible crop insurance contracts…will be paid to the Company on the monthly summary report after the Company submits, and FCIC accepts, the information needed to accurately establish the premium for such … contracts." *Id* A&O subsidies are paid on a "net book premium" basis which is defined by the SRA as: "The total premium calculated for all eligible crop insurance contracts, less A&O subsidy, cancellations, and adjustments." *See* 1999 Standard Reinsurance Agreement (SRA)-Section I ¶ N.

[68] *See id.* ¶ A.2.b. GRP policies key coverage to expected county yields based on National Agricultural Statistics Service (NASS) data rather than individual yields. *See* RMA Online, Group Risk Plan (GRP), *available at* http://www.rma.usda.gov/pubs/rme/fsh_4.html (last visited Feb. 20, 2002).

[69] *See* 1999 Standard Reinsurance Agreement (SRA)–Section III ¶ A.2.c. - 2.d., *available at* http://www.rma.usda.gov/tools/agents/sra99_b.html (last visited Feb. 20, 2002).

[70] *See id.* ¶ A.2.e.

[71] *See id.* ¶ A.2.a.

[72] *See id.* at Section IV. CAT loss adjustment expense was reduced from 11 percent to 8 percent effective with the 2001 crop year. *See* Pub. L. No. 106-224, tit. I, sec. 103, 114 Stat. 358, 365 (codified as amended at 7 U.S.C. § 1508(b)(11) (2000).

[73] *See id.* ¶ B. Reinsured companies are required to collect administrative fees from eligible producers as follows: For CAT policies, the greater of $100 per crop per county or 10% of the imputed premium. *See* 7 U.S.C. § 1508(b)(5)(A). The administrative fee for additional coverage policies is $30 per crop per county. *See* 7 U.S.C. § 1508(c)(10)(A).

[74] *See* 1999 Standard Reinsurance Agreement (SRA)–Section III ¶F., *available at* http://www.rma.usda.gov/tools/agents/sra99_b.html (last visited Feb. 20, 2002).

[75] *See id.* ¶ G. FCIC reduces A&O subsidies in 1.5% increments up to a maximum of 4.5% for data received more than twelve weeks after the final acreage reporting date for the crop where the delay is the fault of the reinsurer. *See id.*

[76] *See id.* Section V ¶ J. A company has 45 days from its date of notification to correct deficiencies or the SRA automatically terminates at the end of the reinsurance year. While suspended, a company may not sell new policies, however, FCIC may require that it continue to service existing policies. *See id.* ¶¶ J.1. - J.3.

[77] *See id.* ¶ M.

[78] *See id.* ¶ W. "Liability incurred, to the extent it is caused by agent or loss adjuster error or omission, or failure to follow FCIC approved policy or procedure, is the sole responsibility of the Company." *Id*

[79] *See id.* ¶ L. The relevant appeal procedures are set out in 7 C.F.R. § 400.169.

[80] *See* 7 C.F.R. § 400.169 (a).

[81] *See id.* § 400.169 (b).

[82] *See id.*

[83] *See id.* § 400.169 (a) - (c).

[84] *See* 1999 Standard Reinsurance Agreement (SRA)–Section V ¶ L.2., *available at* http://www.rma.usda.gov/tools/agents/sra99_b.html (last visited Feb. 20, 2002).

[85] *See id.*

[86] *See* 7 C.F.R. § 400.169 (d). The Board of Contract Appeals is an agency within USDA composed of licensed attorneys who are designated to act as Administrative Judges. *See* 7 C.F.R. §§ 24.1 - 24.2. Generally, Board decisions constitute a majority decision of a three-judge panel. *See* 7 C.F.R. § 24.2.

[87] *See* 7 C.F.R. § 400.169 (c).

A company may also request reconsideration by the Deputy Administrator of Insurance Services of a decision of the Corporation rendered under any Corporation bulletin or directive which bulletin or directive does not interpret, explan [sic] or restrict the terms of the reinsurance agreement.… The determinations of the Deputy Administrator will be final and binding on the company. Such determinations will not be appealable to the Board of Contract Appeals.

Id

[88] *See* 7 C.F.R. § 24.5.

[89] *See* 7 U.S.C. § 6912(e); *See also Farmers Alliance Mutual Ins. Co. v. FCIC*, 2001 WL 30443 (D.Kan.) (dismissing action brought in district court against FCIC because reinsured had not appealed to USDA's Board of Contract Appeals).

[90] *See* United States Gen. Accounting Office, Crop Insurance - Opportunities Exist To Reduce Government Costs For Private-Sector Delivery, GAO/RCED-97-70 at 137 (1997).

[91] *See generally,* Barry K. Goodwin & Vincent H. Smith, The Economics Of Crop Insurance And Disaster Aid, 34, 48 (1995); *See also* United States Gen. Accounting Office, *supra* note 86, at 23 ("Insurance premiums written by participating companies during this same period increased from $747 million in 1990 to $1.6 billion in 1996.").

[92] *See* United States Gen. Accounting Office, *supra* note 90, at 137.

[93] *See id.*

[94] *See id.* at 23 ("The number of companies selling and servicing crop insurance for FCIC has decreased from 27 in 1990 to 16 in 1996 because of business acquisitions and changing business relations.").

[95] *See id.* at 68 - 69. Appendix II of GAO's report reflects that in 1994-95, American Agrisurance was the managing general agency for SRA holder Redland Insurance Company and that Blakely Crop Hail, Inc. was the managing general agency for SRA holder Farmers Alliance Mutual Insurance Company. *See id.*

[96] *See* 1999 Standard Reinsurance Agreement (SRA)–Section V ¶ G.3., *available at* http://www.rma.usda.gov/tools/agents/sra99_b.html (last visited Feb. 20, 2002). The SRA holder must certify that managing general agents are "in full compliance with the laws and regulations of the State" where incorporated. *See id.*

[97] *See Federal Crop Insurance - Insuring the Farm Bureau's Future*, Rural Community Updates (Defenders of Wildlife, Grass Roots Environmental Effectiveness Network Project, Albuquerque, N.M.), Sept. 2, 1999 at 1.

[98] *See* 5 U.S.C. § 552 (b)(4).

[99] *See* United States Gen. Accounting Office, Crop Insurance - USDA Needs A Better Estimate Of Improper Payments To Strengthen Controls Over Claims, GAO/RCED-99-266 at 3 (1999) ("From 1981 through 1998, FCIC paid farmers $14.1 billion for insured crop losses, and in 1998 alone, FCIC paid $1.7 billion.).

[100] *See* United States Gen. Accounting Office, *supra* note 90, at 96 ("NCIS is an association composed, among others, of all of the current holders of Standard Reinsurance Agreements ('SRA").

[101] *See e.g.,* United States Gen. Accounting Office, *supra* note 90, at 34 ("Despite this prohibition [on reporting lobbying expense as crop insurance delivery expense], we found in our sample of company transactions that the companies included a total of $418,499 for lobbying and related expenses in their expense reporting for 1994 and 1995.").

[102] *See generally* United States Department Of Agriculture Office Of Inspector General - Report To The Secretary On Federal Crop Insurance Reform, No. 05801-2-At (1999).

Battles/Cont. from p.3

Premier Mike Harris condemned the Myriad patents and indicated that Canadian laws should be amended to prevent private firms from patenting human genes. Myriad's patent claims were no more popular in Europe, where researchers and clinicians from France, Belgium, Denmark, Germany, the Netherlands, and the United Kingdom filed an Opposition request against Myriad's EPO patents. On October 4, the European Parliament adopted a resolution opposing the Myriad patent.

Compulsory licenses: confronting a patent with a bludgeon, not a stiletto

Instead of clashing with a patent head on, a government can make an end run with a compulsory license, which is a grant of a license without a patent owner's permission. Under the current Trade-Related Intellectual Property Rights (TRIPS) Agreement, Members can issue compulsory licenses that allow local production of generic drugs in the event of a national emergency. Following the recent anthrax deaths in the U.S., Canada announced its intent to impose compulsory licensing on Bayer's ciprofloxacin (CIPRO) and Tommy Thompson, Secretary of the US Department of Health and Human Services, reportedly urged the threat of compulsory licensing to strike a deal with Bayer for the US government to buy 100 million CIPRO tablets at a reduced rate.

According to Representative Christopher Shays (R-CT), Congress would probably back any request from Thompson for permission to bypass the Bayer patent, and after the Bayer deal was finalized, Representative Sherrod Brown (D-OH) introduced legislation ("Public Health Emergency Medicines Act"' H.R. 3235) that would allow the Secretary of Health and Human Services to authorize compulsory licensing of patented inventions relating to health care emergencies. Traditionally, the US has held a dim view of compulsory licenses as shown by another bill ("Comprehensive Trade Negotiating Authority Act of 2001"; H.R. 3005), which declares that one of the principal negotiating objectives of the United States is to make reasonable efforts to address the problem of supplying essential medicines, other than by compulsory licensing.

—Phillip B.C. Jones, Ph.D., J.D.,
Seattle, Washington
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