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# *Bridging the Gap: From Laboratory to Commercial Product*

## Q&A

MODERATOR: ANTHONY SHELTON

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*Tony Shelton:* We've covered a lot of ground today but we now have the opportunity to ask some penetrating questions of the speakers.

*Peter Welters (Phytowelt):* I have a question for Mike Adang regarding your BtBooster. The beauty of the *Bt* toxin is that it's very specific because it has a specific binding site in the gut of insect. By delivering binding sites with your BtBooster, will specificity be compromised? Will there be higher toxicity for non-target insects or even mammals?

*Mike Adang (University of Georgia):* The question is, essentially: does BtBooster affect insect host-range? Well, we haven't seen a change of the BtBooster toxin binding to the insect mid-gut in specificity. The *Bt* toxin still kills the same set of insects and if you have a level of toxin that kills maybe 10% to 15% of the insects, it kills them more rapidly. It doesn't make a caterpillar-active toxin kill a beetle or a mosquito. We haven't looked yet at other lacewings for non-target effects. And we haven't done any mammalian tests. They will be done, but I would be very surprised if it has any effect like that, because it doesn't seem to be altering the basic toxin mode of action requiring receptors, things like that.

*Ralph Hardy (National Agricultural Biotechnology Council):* I want to look at this from the industry side. I have a couple questions. One: what does industry expect from the public-sector research—ARS, CSREES, university research? And two: when industry is presented technologies that come from within and from without, how do you make a decision on which to pursue? How do you manage that?

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*Richard Broglie (DuPont):* Your first question is, what do we expect from the public sector? Certainly, because of what I talked about in the investments and the costs associated with developing the products that we have in our pipeline now, there are plenty of opportunities to look for new products to come into that log jam. The log jam is a good thing if you've got lots of logs coming into that so you can make the right choices, and certainly we know that we can't do everything internally so we are looking for partnerships. We have a number of partnerships with both small biotech companies as well as various academic institutions. The key thing is looking for new traits to come in at that early discovery stage. And your second question: we haven't come across that in too many instances. If you have something internally it's more efficient to build on that because you've already made the investment rather than bringing in something that would be duplicative, let's say, if it was developed externally. But more often than not they are complementary technologies and they provide maybe a first or second-generation product. It's like complementing what we already have in place, which would be probably a more favorable situation to looking at something that was developed externally. We don't have the "not-invented-here" syndrome anymore. We certainly need to continue bringing new things into our pipeline—the recent acquisition of Verdia, for example.

*Wim Jongen (Wageningen Business Generator):* May I go to the other side of the story? It seems now that universities also have the ambition to bring knowledge to the market, to make science work. We see that with the SBIR funding. One question comes to my mind is: when we talk of that part of the system do we do it coincidentally or do we try to structure it one way or the other or make these ambitions really a structural approach of our way of working?

*Bill Goldner (USDA-Small Business Innovation Research Grants Program):* I'm not sure that the question came across fully—

*Mary Pat Huxley (California Community Colleges):* The question is: do we put the structure in universities for ethics and entrepreneurship or let it happen by chance?

*Broglie:* Let me try to address the entrepreneurship part of that and I'll turn over the ethics part. Something quite obvious, at least to me, is that lots of new ideas are being generated at universities and certainly an important link to making those turn into commercial realities is connecting early on with industrial partners. Incubator facilities are important for providing the opportunity for an academic laboratory to move off into an isolated area to continue to develop a technology. Building links early on—so that it's not just by chance that these things develop—with businesses that can pull technologies into the marketplace, is important.

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*Paul Thompson (Michigan State University):* One of my colleagues at the University of Guelph, Dave Sparling, teaches a course on science entrepreneurship. He gets a lot of students from the sciences, most of whom conceal the fact that they are taking the course from their major professors. They have to do that. Many of them take it as an overload and don't tell their professors that they are doing so. This reflects differences in the generations. They recognize the need to do this, whereas their major professors see it as time away from the main topic. And I see a little bit of that in ethics, but not quite as much. And let me also say that, in terms of what we are prepared to teach in ethics, it's not like we have a curriculum that's well developed and widely accepted. In fact—speaking of my own discipline—very few of the philosophy people who are interested in technology and technological ethics are at what are considered to be the leading philosophy departments. There is a certain sense in which philosophy is institutionalized such that it allows us to keep working on problems that are 2,000 years old. And nobody expects philosophy departments to do much, but everybody thinks that you've got to have a good one in order to be a respectable university. So there is no reason for a philosophy department at a top university to do technological ethics. That's not where the action is in my discipline. I don't think that most of you would be able to ring up the philosophy department at your institution and necessarily get anything that would be worthwhile.

*Milt Zaitlin (Cornell University):* A question for Dr. Adang. I used to sit on a committee here at Cornell where we dealt with conflict of interest questions that came up when a professor's company invested in his lab and graduate students were doing research directed at the company's interests. How do you address those kinds of issues?

*Adang:* During my talk I mentioned that the university has developed a document that addresses some of these issues. The university communicates any concerns to the professor—providing the document and then sitting in a group that reviews it with the professor. Then the professor makes it known to the graduate students and others in the lab where the lines are drawn between what is company-sponsored research versus other publicly funded research. As a policy, I have not had students work directly on company projects with the exception of one graduate student who is a co-inventor of BtBooster technology; he has continued working with this. I have updates with my dean in the college, along with Cliff Baile who is the executive of the company. We have open communication and disclosure of what's going on, what's sponsored by whom and who is doing what within the laboratory. I have no restriction on my people in terms of what they present, *etc.*, to the public. Did I answer your question?

*Zaitlin:* (inaudible)

*Adang:* You don't allow the company to actually put projects in the laboratory?

*Zaitlin:* That's right.

*Adang:* Yeah, different degrees of policy are in place. There's no "blanket" across the US universities. I had this discussion a couple of weeks ago at a meeting with colleagues from Iowa State, University of Connecticut, University of Kentucky and a couple other places—you might call it an entrepreneurs' club. We talked about the different policies universities have. Maybe there should be a standardized way of addressing this issue in ag colleges and universities.

*Bruce McPherson (Pennsylvania State University):* Can you look into your crystal ball and give us an assessment of where you think the kind of relationships we are talking about are going? We heard positive information about some federal funding sources within the last month. The *Chronicle of Higher Education* has reported that industry investment in university research has actually declined over the past 3 years. It's taken its first dip in quite a while. What's the trend line here? We talked in the last 2 days about the difficulties of getting venture capital for biotech projects, particularly in agriculture. What do you see the slope of the line of these kinds of relationships being over the next several years?

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*Thompson:* This is not my area of research, but I know some people who do work on this. Not just in the biosciences—it's even in the arts and humanities—university faculty are becoming overwhelmingly involved in various kinds of for-profit entrepreneurship activities. It's grown dramatically over the last 20 years. Increasingly there is pressure from faculty at almost all institutions to facilitate this kind of thing. I've seen data from economists and others who study this and there's no suggestion that this trend is abating. You guys talk about patents and in my line of work we talk about copyrights but, increasingly, professors are doing things like copyrighting syllabi—trying to protect intellectual property in something as simple as a course syllabus.

*Goldner:* There's a lot of room right now for speculation. You asked a very good question. I was on the off campus faculty at Rutgers before I came over to USDA—like what Mike was referring to, a lot depends on the culture of the university that you are working with—whether or not you are encouraged to develop technology, develop relationships. When I was at Rutgers certainly that was strongly encouraged in the department that I was involved with to try to be relevant. I'm in the Cooperative State Research Education Extension Service and we have the National Research Initiative, we have the SBIR

program, we have other grant agencies that support grant mechanisms that support all types of university research activities, and the internal discussion that we have is: how can we remain relevant? It's the kind of question that we all need to ask ourselves, whether from the university perspective or the industry perspective. The industry perspective is sort of self-limiting in that if you aren't relevant in industry you are gone. You can see from this meeting the synergies and needs to interact among the academic communities, the government in all its permutations and the private sector. That's certainly very important and when we all start thinking like that we will move a little bit more easily towards that. That's not to say that there isn't a role for research in the university systems outside of industry. I think there is a very, very strong need for that. There is no question about it. A lot of funding goes into basic research, but mission-oriented research is also very important.

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*Rick Brenner (USDA-Agricultural Research Service):* The issues of commercial success and economic competitiveness are complicated. That has come out loud and clear over the last few days. These partnerships truly are critical if we are going to succeed in this, whether we are starting with a small operation in Geneva, NY, or any of the 150 university research parks across the nation or even in the federal laboratories. It is complicated, it's complex, but it's also essential that we find some solutions to that. I see our role in part is to help develop these public/private partnerships and that's truly what this is about. None of us individually has all the right pieces. And that includes the funding issues. Some of that can come from the federal sector, but a lot of it isn't going to come from the federal sector. The private sector may want to contribute to that funding, but who's going to manage the risks? Who's going to absorb some of that? That is another federal role. Regulatory issues are also involved. How can we not make all of these a no-go just because the regulatory hurdles are far too high? We've begun talking about having workshops where we will pull all of the complementary aspects together that are needed to really be successful in this and that's going to be the funding issues, the research issues, the regulatory aspects. And where we might have an opportunity to begin looking at that is in the current hot-topic items, is in the energy issues, because every one of us feels the need to be successful at coming up with innovative solutions to be less dependent. I can tell you that in ARS we've been getting a lot more interest from private-sector companies talking about what our research capacities may be to help on some of these more basic research issues. And I'll also tell you that we've had venture-fund people calling us and asking us. We have clients interested in this particular area: "What can you tell us about it?" So, there's

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enough interest. The question is, is there enough momentum to take this through? From the energy standpoint, that is going to depend on what the price of the barrel does. From my perspective we are going to move forward. We're going to see more creative measures to bring all of these complementary assets together. One of my concerns is: how do we manage those conflicts of interest, especially in the public sector? There are ways to do it but it will involve networking and getting together and talking about these issues.

*Huxley:* There is something I want to share before we close. When a company chooses to relocate, the choice of location includes appraisal of whether a ready and well-trained workforce is available. Also, depending on company size, seven to fifteen workers support upper management and/or upper scientific investigators. Of those seven to fifteen people who support each person on the higher level, about 30% are technical. The question then becomes: once the company has an idea, gets first funding, second funding, proof of concept, begins to commercialise, are the worker bees available? Generally speaking, the answer is “no.” I want to leave that with the group. It's wonderful to have these ideas, tech transfer, *etc.*, but is it possible to bring the product to market and for the company to grow with the right workforce? In many cases, probably not—not right now anyway. That needs to be looked at.