

BOARD OF REGENTS, STATE OF IOWA

University of Iowa
Iowa City, Iowa

ECONOMIC DEVELOPMENT COMMITTEE

R. Wayne Richey Ballroom

February 2, 2005 - 1:00 – 2:00 p.m.

Persons in attendance (not all-inclusive):

Committee members: Robert Downer (Chair), Amir Arbisser, Mary Ellen Becker, Michael Gartner, Owen Newlin, Jenny Rokes
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Absent members: Sue Nieland

Regent Downer called the meeting to order, which convened at 1:05 p.m.

ECO 1. Approval of Minutes (Chair)

- a. November 3, 2004
- b. December 14, 2004

Regent Downer deferred action on consideration of the minutes from November 3, 2004 and December 14, 2004, as they were not available for review.

ECO 2. Biosciences Alliance Status Report

Regent Downer introduced Vice President Decker to present the status report on the Biosciences Alliance.

Comments from Vice President Decker

Before proceeding with the subcommittee reports, Vice President Decker mentioned that the range of subcommittee issues has included looking at:

- the scientific platforms that were proposed by Battelle,
- a possible financial structure for the Alliance,
- a governance structure for the Alliance,
- a communications plan for the Alliance, and
- a commercialization plan for the Alliance.

Each of these areas have been examined by various subgroups. Vice President Decker turned the discussion over to Randy Pilkington, who had a great deal to do with the governance, to speak to the issue, as well as the steps that have taken place since the last meeting.

Mr. Pilkington said the challenge he faced was to put together a governance structure for the Bioscience Alliance. This ended up being a relatively large board; they had to balance inclusion of all the groups with the ability to conduct business. The balance included private industry, the associates, the biotech area and University expertise.

The Board has now been formed; a 40+ member organization. The Executive Committee will do a lot of the operations with a more reasonable size of nine, making most of the decisions, with information flowing up from each of the platforms. The first board meeting has been scheduled for February 10, 2005 in Ames, Iowa. The governance structure is in place, in operation and will start to meet.

Vice President Decker pointed out that each of the University Presidents is a member of that Board, as is Regent Downer. Vice President Decker asked Regent Downer to give an update for the Commercialization Subcommittee.

Update on the Commercialization Subcommittee

Regent Downer said the Subcommittee has had one meeting and he is a co-chair with Ted Crosby of Monsanto. Another meeting is scheduled for Friday, February 4, 2005. A number of areas for the Subcommittee to focus on have been recommended. Regent Downer feels they have assembled a very good group of people for the Committee; people involved in venture capital and otherwise have been involved with the start-up of high tech businesses. Although in the early stages of that endeavor, this was the last individual committee to start work. They are moving ahead and Regent Downer says they will have something more definitive to report by the next Economic Development Committee meeting.

Vice President Decker asked Jim Bloedel to report on the Science and Platform Subcommittee. He attended a meeting with Dr. Bloedel the day before and wanted him to share the new information.

Update on the Science Subcommittee

Dr. Bloedel said he was asked to chair the Science Subcommittee. This committee's charge was to generate the leadership for the various platforms, which are really the drivers for the Battelle "road map".

The Subcommittee was put together consisting of two Deans each from the University of Iowa and Iowa State University who would be closely associated with those platforms. They had representatives from all three Regent Universities. Also, an equal number of representatives from different industries related to the platforms.

They have had several meetings, usually by teleconference, to discuss strategies for evolving the leadership. They decided on a plan where there would be both an academic co-leader and an industry co-leader. Each of the seven platforms will be led in that fashion. One of the platforms, because of the collaboration between Iowa State University and the University of Iowa involved with that platform, will have a co-leader from each campus.

The Subcommittee established guidelines for the platforms in terms of issues pertaining to deliverables and issues pertaining to portfolios. The meeting of February 1, 2005 was very productive, where the Science Subcommittee and the leadership from the platforms were brought together. They met over a four hour period and worked through issues pertaining to leadership directions. Among these platforms, they established mechanisms for evolving and deciding priorities for funding, should they have the opportunity to do so. They also made some recommendations pertaining to governance structure as it relates to the interface between the platforms and the Bio Alliance Board.

The leadership of the platforms have now been charged with the responsibility of putting together their teams and coming up with strategies that can be implemented when funding becomes available for this initiative.

Regent Downer asked Dr. Bloedel if he could describe a little more fully the term “platform” and indicate what the significance is of each one of these platforms and what’s going to be occurring within each of the platforms.

Dr. Bloedel said Battelle did a very extensive study, utilizing both literature reviews, as well as interviews on all of the Regent’s campuses, to assess where the strengths of the Universities were relative to the expertise in the state. Through that analysis, they determined that there were seven areas in which the State of Iowa had particular advantages in moving forward and developing economic initiatives in these areas.

These seven platforms are:

- Integrated Biosecurity,
- Integrated Postgenomic Medicine,
- Integrative Drug Discovery,
- Bioimaging,
- Bioeconomy, which is really biomass and biorenewables,
- Animal Systems and Animal Genomics, and
- Advanced Food and Feed.

These platforms are intended to be target areas for the investments that would be funded as part of this initiative. Each of these initiatives is hosted by either the University of Iowa or Iowa State University. The intent is that these platforms be highly collaborative. One of the other actions of the committee deliberations yesterday was to ensure that there would be representatives from all three Regent Universities, as well as industry scientific leaders on these platforms, with a very high expectation for deliverables as these programs evolve.

Regent Downer asked Gary Steinke, Deputy Executive Director, to update the Committee on the progress in the Legislature with respect to the funding that's going to be necessary to bring the Biosciences projects to fruition.

Comments from Gary Steinke, Deputy Executive Director

Mr. Steinke said that prior to the Governor's budget being released, the leaders in the Legislature in the area of Economic Development and those who have "carried the water" for the Regents on the Economic Development programs, have been less than positive about whether or not there would be a Battelle bill; a bill which would take the recommendations of the Battelle Report and translate those recommendations into dollars for research, as was called for in the Battelle Report.

He said it seemed at this point that as far as Biosciences funding, the Regents projects will probably come through the broader umbrella of the Iowa Values Fund. He thinks there will be an effort to broadly fund the Iowa Values Fund programs, then dedicate a portion of those dollars to the Universities for Biosciences initiatives.

Regent Downer asked if there were any other questions. There were none.

ECO 3. University of Iowa Grow Iowa Values Fund Projects Status Report

Comments from Bill Decker

In the December time frame, the University brought to the Committee's attention a plan to utilize the \$4 million the University then understood they had from the Values Fund, to use those dollars to accomplish most of the original objectives for the program. Those two projects were:

- Upgrading of the Center for Biocatalysis and Bioprocessing to cGMP capability, and
- Establishment of a wet lab business incubator facility called BioTic.

Due to some changes in company directions at the Oakdale Research Park, there were two buildings that could be looked at for leasing to immediately establish the capabilities. One of the buildings previously housed a company named Apovia and has in it an already operating, essentially cGMP-certified facility. The beauty of taking over this lease and purchasing the existing equipment is that they accomplish the CBB upgrade objectives very rapidly, approximately 12-18 months ahead of what otherwise would have done. They are able to do it in a somewhat larger space that includes offices and other amenities for working with companies in addition to the laboratories.

The third, and very positive aspect of this opportunity, is that they believe they may be able to keep one startup company in progress through taking over the facility and hosting them as their first client.

Vice President Decker said he toured the facility recently, and called it a remarkable place. They have been lucky enough to be able to hire one of the individuals who previously worked

there, who is very knowledgeable with the certifications and validations. In the agenda for the Committee's meeting, there is an approval of the lease to move forward with this. There is a temporary lease in place, which will transition to a formal lease, if the Committee approves going forward.

The other lease on the second building is a similar story. It contains wet lab space that is already configured. What has been asked for this is to change the lease that was already in place to include an option to buy.

The situation the University is in now with the lease and option to buy is that it buys a few months to see how that situation plays out with the legislation. If it does not play out, the University would proceed with the plans as was brought to the Committee: implement the Biotic quickly in the space available, if the rest of that money should become available, the University will quickly decide how to proceed with a larger amount of money and possibly incorporate that space with some other plans.

Vice President Decker said they were excited to be able to bring these items to fruition more rapidly than had been originally imagined.

Comments by President Skorton

President Skorton commented that there were a couple of Board members who were not on the Committee a year ago when the University began setting the stage for this. President Skorton asked Regent Downer if he could repeat the context of this issue, as the acronyms were "mind-numbing".

The College of Pharmacy at the University of Iowa has for decades had one of the most prominent national capabilities to actually manufacture drugs for human use in clinical trials. He said it's very unusual for that capability to be present in a University; normally it's in a company. Dozens of companies over the years, from all over the world, have used that capability on a contract basis.

As the newer methods of doing drug development have evolved, some of them involve the use of microorganisms. The Center of Biocatalysis and Bioprocessing, which is a prominent interdisciplinary center at the University, has not had the documentation, equipment and personnel to become FDA certified as a so called "good manufacturing practices" facility, which is what GMP stands for.

Even though the University is talking about the focused pointed details of the lease, if and when this is done, and when the capability is brought up to speed, what it means is from the point of view of attracting or retaining industry interested in drug development, that Vice President Decker's organization and the University will have the capability of doing this in the traditional way, as well as in the newer way, linked to microbial or microorganism basis for producing proteins that then could be turned into drugs. It would be a substantial increase in the capability of the Regent's enterprise to deal with the drug development industry. To make sure that context is understood, while they are focusing on the details of the lease, President Skorton commended Vice President Decker and his staff in figuring out ways to utilize the reduced funds available from the Grow Iowa Values Fund. This is still a generous amount of

money that will get the enterprise to that same goal, although in a different way than originally thought.

Vice President Decker commented about the Battelle Report and the Biosciences Alliance. He said that one of the platforms in the Biosciences Alliance is advanced drug discovery and development capabilities. The Battelle Report had identified the University's Center for Biocatalysis and Bioprocessing, the Center for Advanced Drug Development and a pharmaceutical services division in the College of Pharmacy, as a set of resources that President Skorton was describing. This put the University in a very unique position in the academic world, being able to offer the kinds of services that were described. This is a direction that's very compatible with those issues and also positions the University very well for additional economic development activity.

ECO 4. Biotechnology Risk Assessment Project Status Report

Comments from Jim Bloedel

Dr. Bloedel said he was pleased to present the report, because he thinks it is a real success story to the value of collaboration between the two research Universities. This is a project that resulted from a grant from the Iowa Department of Economic Development, which is under the leadership of a Risk Assessment Institute at Iowa State University called BIGMAP, (Biosafety Institute for Genetically Modified Agricultural Products), which is being performed in close collaboration with a research team at the University of Iowa.

There are five deliverables specified in this Agreement. He will give a couple of sentences on each deliverable so that the Committee understands the breadth of the project and the results to date. This is a compilation of the progress to date. There has been a lot of activity and a lot of productivity associated with this research.

Deliverable 1 – The classification of plant-made pharmaceuticals near commercialization, based on information available in the public domain, similar to a data mining project. There were 24 compounds approved by APHIS (Animal and Plant Health Inspection Service) in the area of pharmaceutical and industrial corn. Iowa State's role was to perform a survey on all 24 of these compounds, looking at such issues as structure, function, the clinical trial data that may be in the literature, etc. The University of Iowa was charged with the responsibility of undergoing a toxicological review of six of the compounds. The analysis of two of the compounds has been completed and the remainder are in the pipeline.

Deliverable 2 – Complete risk assessment of two plant-made pharmaceutical proteins that would require identification of human health risks, as well as benefits related to production. The two plant-made pharmaceuticals chosen for this analysis were Enterotoxin and Aprotenin. The risk assessment for each of the compounds consisted of two elements; one a quantitative exposure estimate and the second, a human health hazard assessment. The exposure component being addressed by scientists at Iowa State University and the health hazard analysis being undertaken at the University of Iowa. The risk assessment for Enterotoxin is entirely complete and there has been a manuscript prepared for publication in

the public domain. The risk assessment for Aprotenin is well underway and is nearing completion.

Deliverable 3 – To identify and act on knowledge gaps where added research is needed. One of those gaps is pollen flow in corn. It was felt by the research team that this was a critical enough area to require that graduate students be hired to work together with faculty to address specific projects in this area. They addressed two kinds of projects: practical field type analysis of pollen spread. In addition, there were two types of simulations; simulations on the relationship between pollen flow and field management and a simulation done on some economic factors related to the establishment of rates for insurance for individuals who would grow plant-made pharmaceuticals.

Deliverable 4 – To establish a template for risk assessment methodology for the plant-made pharmaceutical proteins. The templates have been under review and development. The template related to the exposure component has basically been finished. The template related to hazard classification and assessment is near completion. Those two components will be put together in the template in the near future.

Deliverable 5 – To disseminate information on risk analysis through symposiums and public forums. This has gone extremely well. There were a dozen structured presentations made over the roughly 2½ years the contract has been viable. To give a couple of highlights from that activity, a symposium on corn-produced pharmaceuticals and industrials was held in April, 2004. It was extremely well attended by over 175 participants, nationwide, including a number of individuals from the USDA and FDA. This symposium received a lot of publicity. Another example is the fact that leadership chaired and organized the session at this year's Bio Conference, an international conference on Biotechnology. This was facilitated by the Iowa Department of Economic Development and drew a great number of individuals for the session. The scientists are not only performing the research and reporting them, but they are making this research available through published manuscripts and manuscripts open to the public domain, so that this information will be widely disseminated as these final stages come to completion.

Regent Downer said that this was an area that Regent Newlin has been intensely interested in and has extensive scientific background, because of his work and education. Regent Newlin had two questions. He said he appreciated the work that has been done in a collaborative effort and asked:

- (1) What the name of the platform that Iowa State University and the University of Iowa are jointly chairing, and
- (2) How safe were the two proteins, Enterotoxin and Aprotenin.

Dr. Bloedel said the name of the platform is Integrated Biosecurity. The safety assessment to date suggests that the Enterotoxin, which is used to treat gastric infections that result in diarrhea, as well as some respiratory infections, is relatively safe. It has some immunogenic characteristics that can create some reactions to the drug, but overall, it is a fairly safe compound. To date, the assessment of Aprotenin suggests, as has been touted in the medical literature, it is used primarily at this point with high risk cardiac patients in applications related to cardiac surgery. It is somewhat immunogenic, in that it will precipitate

allergies to the drug if taken repeatedly. That type of usage is likely to be discouraged. It's a little bit higher risk compound with a few more hazards associated with it than the Enterotoxin.

Regent Newlin asked if neither one of them will move forward because of the allergy issue. Dr. Bloedel said both are already approved drugs. The issue is the capacity to generate those drugs in a plant-made pharmaceutical framework.

Comments from President Skorton

President Skorton responded to a portion of what Regent Newlin was asking. Some of the recent concerns of previously approved drugs that turn out to have some issues later, is what has been in the headlines about the FDA. This concept of so-called post-market surveillance, where a drug or a chemical is approved and used by physicians and turns out to have some issues later, is a field that everyone is still learning how to deal with; how to get information to practitioners and how to get to the bottom of what the cause of it is and what to do about it.

The beauty of the work coming out of Iowa State University and being done collaboratively is to have a more scientific basis of making some of those determinations. The other approach is to try to keep track of clinical experience, if someone has a negative reaction, it depends on the practitioner to voluntarily report that, unless there is a formal post-market surveillance mechanism. Speaking as a practitioner and not as the President of a university, this kind of an effort is very helpful, because it is a more scientific, mechanistic way to figure out risk assessment on some chemicals.

Regent Arbisser said the post-market assessment is actually a potentially useful area to the University to be actively engaged in things that are already on the market. He said a lot of individuals in the private sector are involved with collecting information and there are some very strict rules, but feels it is potentially an income stream.

Regent Becker said she appreciated the explanation because it was easy for her to follow what the Universities are doing. She feels the importance of this work and the collaboration between the two Universities is exemplary. She said she sees how this will fit in with the other things that the Committee will be doing related to the Battelle Report. She thanked Regent Newlin for drawing the Committee's attention to this issue a couple of meetings ago. She feels it is very exciting work and to have this be done and moving forward prior to some of the other issues coming to light in the Battelle Report was great. She thanked both Universities for their work.

ECO 5. Review of Patent and Related Policies

Comments of Regent Downer

For those individuals who have followed the work of the Committee, even going back to the time that it was a priority study group, there has been consideration given to reviewing the patent policies of the three Universities, with an eye toward looking at the circumstances

under which research developed at those institutions could be commercialized and that faculty members involved in that research could receive a personal benefit, by virtue of that commercialization. Because of the direction that the Committee has received with respect to the Values Fund and the Battelle Report, this matter has moved somewhat off center stage, but is now before the Committee again, as an initiative of the presidents of the three Universities. They have all indicated that they were personally going to take charge of moving this forward, evaluating the policies at each of the schools to make certain that they were friendly toward commercialization and were such that they would play a role in the economic interests of the state, that they would collaborate among themselves to get the best parts of all of those policies in front of the other institutions and see where change is needed. He thinks there have been some very positive developments coming in this area and asked the three presidents for any remarks that they might care to make as to how they see this process moving forward.

Comments of President Geoffroy

He said the University feels they have an excellent patent policy at Iowa State University, but like everything, there is always room for review and improvement. They are enthusiastic about taking a periodic review of the University's policies and determine if there are areas that can be improved.

Comments of President Skorton

He said the University's activities in technology transfer have been oriented quite a bit toward human health and medicine by the nature of having the Carver College of Medicine and UIHC, College of Nursing, College of Dentistry, College of Pharmacy and College of Public Health Activities on campus. Because of the national nature of drug development, medical device development, etc. the University has been criticized for not paying enough attention to opportunities in the State of Iowa. The University has also been criticized by some of their own faculty that policies were not "friendly" enough to local entrepreneurs and to moving these things within the state.

Part of the plan that was developed by Vice President Decker was to do such a review that is being discussed, to review not only the patent policy itself, but other University policies and procedures. He said he appreciated the fact it was changed to a presidential initiative and very supportive of it, because he feels it involves a wide swath of University activities and goes beyond the strict narrow pointed issues related to patent policy, per se.

The other comment he wanted to make was to do such a review carefully, enterprise-wide, as President Geoffroy, President Koob and others have pointed out in the past, would require a national perspective, as well as a State of Iowa perspective, dealing with national patent policy and Federal laws, policies and procedures that affect the University's use of Federal funds for many of these activities. The University is anxious, willing and ready to do that analysis.

Comments of Vice President Decker

Vice President Decker said that the University has already taken a number of steps. The intellectual property policy has been revised in the last few years and now includes at least two incentives for faculty members to receive further consideration for their inventions. That provides incentive for them to more aggressively look at technology transfer opportunities. Their promotion and tenure policies now include at least acknowledgment of patents as an important portfolio consideration, which provides additional incentive.

He reiterated that last October he charged a group with examining the remainder of the policies, conflict of interest, use of space and any number of other policies. He has already received an initial report from them about ways in which those policies might be slightly adjusted and possibly ways in which the University can provide the faculty with some assistance in working through management practices for abiding by the policies. He feels the University is well down the road toward the very objectives that the Presidents have put in place.

Comments of President Koob

President Koob said the past summer, the University undertook a reorganization in the Office of the Provost to add an Assistant Vice President of Sponsored Programs, making use of a vacancy. There was not a new position in the office, but a reconfiguration of a position to be more responsive to the needs of the state. The University is well into that search and are narrowing down the final candidates.

At the same time, they have undertaken a review of the patent and intellectual property transfer processes. It seemed appropriate to do this as a transition in personnel is being made.

The faculty characterized was that the present policy is generous and stimulating and the University welcomes the opportunity to continue the review. He feels this gives them an opportunity to compare it in the context of the other two institutions.

Anticipated Issues for Next Committee Meeting

Regent Downer said he thought the Committee would be getting updates and moving forward on those items that were reported at today's meeting. Matters will certainly be considerably clearer with respect to what the Legislature is doing with respect to the Battelle Report and also what is being done in the various platforms and other areas. Similarly, the other projects the Committee has talked about should be moving forward.

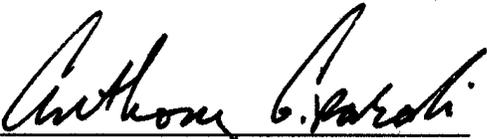
Regent Downer took the opportunity to welcome Michael Gartner to the Board and to say they are looking forward to his service with the Board. Mr. Gartner has had experience in many important positions, both in the public and private sector, including most recently being the Chair of the Vision Iowa Board. While that has not been involved in exactly the same type of economic development arena that the Committee is involved in, it certainly does relate to that and also making the State of Iowa a better place in which to live and work.

Regent Downer asked if Mr. Gartner had questions or comments about the things that he heard during the Committee meeting or suggestions as to how they could move forward.

Comments of Mr. Gartner

Mr. Gartner thanked Regent Downer and the Board. He felt the wisest thing for him to do was to sit and listen and try and soak up as much information as he could. He didn't feel he was in a position to offer any advice to an experienced and valuable Board.

Regent Downer asked for further business to come before the meeting. Having none, Regent Downer adjourned the meeting at 1:58 p.m.



Anthony Girardi



Gregory S. Nichols

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