Minutes*

Senate Research Committee
Monday, April 11, 2005
1:15 - 3:00
238A Morrill Hall

Present: Gary Balas (chair), Mark Ascerno, Dianne Bartels, (George Green for) Victor Bloomfield, Dan Dahlberg, Kathy Ensrud, Genevieve Escure, Steven Gantt, Michael Hughey, Paul Johnson, James Luby, Timothy Mulcahy, James Orf, Mark Paller, Mira Reinberg, Thomas Schumacher, Charles Spetland, George Trachte, Barbara VanDrasek, Jean Witson

Absent: Richard Bianco, James Cotter, Christopher Cramer, Sharon Danes, Robin Dittman, Maria Sera, Virginia Seybold, Michael Volna

Guests: Professor Susan Wolf (Chair, Consortium on Law and Values in Health, Environment & the Life Sciences), Regents Professor Ronald Phillips (Director, Center for Microbial and Plant Genomics); Professor Ken Heller (chair, Senate Committee on Social Concerns); Ed Wink (Sponsored Projects Administration)

Other: Melinda Sewell (Office of the Vice President for Research)

[In these minutes: (1) intellectual property and essential medicines; (2) strategic planning; (3) secrecy (openness) in research]

1. Essential Medicines and University Intellectual Property

Professor Balas convened the meeting at 1:15 and welcomed Professor Susan Wolf, Chair of the Consortium on Law and Values in Health, Environment & the Life Sciences. He noted that this issue has been on the agenda several times in the last three years and he asked Dr. Paller to summarize it.

The issue is about intellectual property the University owns and the University's responsibility for ensuring access to that intellectual property in developing countries, Dr. Paller told the Committee. This first came up with respect to an anti-AIDS drug developed at the University (Ziagen), now it is arising with crops. In the case of the drug, it is one of a number of HIV drugs; the general issue is how pharmaceutical companies sell these products in third-world countries: some individual will not have access to the medicines because of cost. The question is whether the University should take steps to promote access, whether in patenting, in licensing, or in trying to influence pricing.

The background to this is the Bayh-Dole Act, which lets university inventors keep title to intellectual property even if federal funds were used in its development; Bayh-Dole includes a RESPONSIBILITY on the part of institutions to commercialize intellectual property. The Act also allows the federal government to take back title to intellectual property if the university fails to commercialize

* These minutes reflect discussion and debate at a meeting of a committee of the University of Minnesota Senate or Twin Cities Campus Assembly; none of the comments, conclusions, or actions reported in these minutes represents the views of, nor are they binding on, the Senate or Assembly, the Administration, or the Board of Regents.

intellectual property or if it is in the national interest to do so. One question was whether the University should, via our licensing agreements, try to force the hand of manufacturers to ensure access by underdeveloped countries or wait to see whether the federal government would do so. There has been discussion at NIH about whether it is appropriate for the government to march in so that products can be sold in third-world countries at lower prices.

The conclusion was that Bayh-Dole never envisioned action with respect to the prices at which goods were sold. The only reasons for marching in and retaking title would be for reasons of national defense or because the institution was doing nothing with the intellectual property—not because people were unhappy with the prices. That means the question is thrown back to the University: does it have the responsibility to put language in licensing agreements about prices (especially for essential medicines, which are on a list compiled by the World Health Organization and said to be necessary for a well-developed medical system)?

The question is whether the University should renegotiate existing licensing agreements and if it should insist, in the future, that companies make essential medicines available to third-world countries free or at low prices. Dr. Paller described the difficulties the University had dealing with Glaxo in obtaining the royalties for Ziagen. One problem is that the University cannot conduct the large-scale trials necessary to develop drugs for marketing on its own; it needs large pharmaceutical companies (or, in agricultural research, crop companies) because the process is too expensive. So it is difficult for the University to act unilaterally.

The discussion about essential medicines was left previously at whether the University could develop a consortium among similarly-situated institutions (which would have to be led by the Vice President for Research) or pursue the difficult task of renegotiating licenses or inserting a clause in future contracts. For many contracts, such language could be a deal-breaker, because the intellectual property is not that attractive at the outset; only 10% of these products get to market. Agricultural inventors have come up with an attractive way to deal with this issue, the organization of PIPRA (Public-sector Intellectual Property Resources in Agriculture), which is developing a database of publicly-available technologies and creating technology packages with freedom to operate.

Vice President Mulcahy said that in his view a unilateral effort would be ineffective. He was involved in developing a consortium dealing with agricultural products before he came to Minnesota; he said he did not know if that was comparable to dealing with pharmaceuticals. He initially thought there was no way that companies would give away what they could sell, but when the consortium talked with the companies, they learned that in certain areas of the world (e.g., third-world countries) the companies did not see themselves as having a market so were not reluctant to let products go cheaply. The decision represented a challenge to their business principles, and there were tax status questions, and the companies actually preferred to have language in the agreements so they could say that the agreement requires them to do certain things. That does not mean that they would make crops available that they could sell on the world markets. There may be a difference with drugs, Dr. Mulcahy said, which are a product and may not be analogous to crops. He said he thought the consortium arrangements were among the best he had seen and they made people feel good about being at the University of Wisconsin, trying to get the benefit of something to people who could not afford it. This also helps to combat the impression that the universities are only in research for the money.

Professor Balas asked Vice President Mulcahy if he would find out where things stand in the CIC regarding initiatives in the CIC or nationally about the establishment of essential medicine policies/contract language being developed by universities. Dr. Mulcahy agreed to do so.

Professor Wolf next explained that she is the chair of the Consortium on Law and Values in Health, Environment & Life Sciences; she noted that one of the founding members of the Consortium was the center that Professor Phillips directs, the Center for Microbial and Plant Genomics. She commended the Committee for looking at these issues. There is a copious literature about them, she said, and the University need not feel alone in trying to deal with them, especially if they are defined more broadly than essential medicines. They have become essential life science technologies, which includes agriculture as well as medicine.

The Consortium sponsored a meeting with Professor Phillips's Center on the agricultural issues. Professor Phillips and others subsequently made progress in drafting humanitarian language that could be included in University contracts. Universities do have ethical obligations, Professor Wolf said. There is a large literature about the ethical responsibilities of public organizations, including responsibilities to act as a good steward of public funds, and conducting research ethically. The question is not whether a university has ethical obligations but what the institution's obligations are and how are they are to be enacted—questions especially pertinent for public, land-grant institutions.

There are two questions on the table, Professor Wolf told the Committee. One is how people at the University should deal responsibly with intellectual property issues and interact with these humanitarian efforts. What is in line with the University's mission? Analysis of that question is a worthy task. The second question is how to institutionalize the process of addressing the policy and ethical issues raised by intellectual property at this University. This Committee is important but it only meets occasionally; it is important that these issues be part of someone's job.

The Consortium on Law and Values in Health, Environment & and Life Sciences is composed of seventeen centers and programs and takes on controversial questions. The Consortium itself, however, never takes positions and labors to offer balanced programming.

Professor Phillips next reported that the Center for Microbial and Plant Genomics held a symposium that Professor Wolf referred to on intellectual property relative to biotechnologically-derived crop variations and their health implications. The impetus for this symposium came from intellectual property issues that arose in the attempt to make "golden rice" (a rice high in pro-vitamin A) available to the developing world. To highlight the importance of rice of high nutritional value, he mentioned participating in a conference of agriculture ministers in Bangladesh; one of the ministers said that "rice is life." That is true; one-third of the world eats rice. But white rice does not have pro-vitamin A, so as a result 500,000 children go blind every year because they lack vitamin A, two million die because of vitamin-A-related malnutrition, and an additional 600,000 people are malnourished, many living on less than $1 per day and unable to afford foods that could provide pro-vitamin A. Golden rice was developed to correct this pro-vitamin A deficiency for those who live largely on rice.

Advancing golden rice to the developing world was a challenge, Professor Phillips said, because it involved dealing with 70 patents held by 32 different organizations. It took about 18 months, and in that period a lot more people went blind or died. A company interested in selling golden rice in the developed world negotiated with the patent-holders to make the rice available to the developed world; the

scientist inventors, the company, the public funding agencies, and others formed a Humanitarian Board and set rules so they could get the rice to third-world countries. At the same time, people are moving ahead on research to develop new versions of golden rice. This problem, however, leads one to think what will happen with the next product, when there are again likely to be significant patent problems.

The situation is that 75% of the biotechnology patents in agriculture are held by six companies and people worry about who owns the food supply. However, although only 3% of patents are held by public institutions, about 24% of the agricultural biotechnology patents are held by public institutions. The McKnight and Rockefeller Foundations have funded the discussions forming PIPRA. Professor Phillips has recommended that the University join PIPRA, although that has not yet happened. A Policy Forum piece in Science signed by six university presidents, the presidents of the Rockefeller and McKnight Foundations, and the presidents of two major plant science research institutes had urged action in regard to intellectual property issues in agriculture. Professor Phillips also reported that the Board of Trustees of the Donald Danforth Center for Plant Science in St. Louis had adopted a "humanitarian clause" to be included in their contracts.

The Center for Microbial and Plant Genetics together with the Consortium on Law and Values held a symposium at the University on April 29, 2004, entitled "Intellectual Property Rights for the Public Good: Obligations of U.S. Universities to Developing Countries." The symposium was funded by the President's 21st Century Interdisciplinary Conference Series, and the proceedings were published in the inaugural issue of the Minnesota Journal of Law, Science, and Technology as well as via an invited article in The Scientist. There was a consensus at the symposium that there should be humanitarian clauses for university intellectual property agreements. Interim Vice President Hamilton encouraged the effort. Professor Phillips said he and Professors Jim Chen, Ruth Okediji, and Dan Burk of the Law School developed language for a humanitarian clause and sent it to Dr. Hamilton; Professor Phillips said he hoped it would receive a wider airing, and was pleased to bring the activity to the attention of the Research Committee. Inserting such language in contracts would be in keeping with the University's role in producing public goods for society. Professor Phillips read the proposed "humanitarian clause": "The University of Minnesota shall diligently and in good faith negotiate the terms of license agreements to provide affordable access to University of Minnesota-generated technologies that are of potential benefit to developing countries."

The Committee has not seen the proposed language, Professor Balas pointed out. Dr. Sewell said that the Office of the Vice President for Research was working on revising the intellectual property policy, including the humanitarian clause provision, but that effort was put on hold during the transition from Dr. Hamilton to Dr. Mulcahy. The office will take it up again now that Dr. Mulcahy is in office.

Professor Escure asked if transgenic golden rice is genetically-modified (it is). She said it is her understanding that there is no consensus on genetically-modified organisms and that the benefit is to developed countries, not developing countries. Professor Phillips said that there is a consensus that genetically-modified crops can be worthwhile. There are strict biosafety rules that respond to public concerns. Transgenic varieties must go through rigorous approvals, he said, and they hope to have golden rice out in 3-4 years. There is a lot of public concern about genetically-modified crops but plant geneticists support them, as does the International Rice Research Institute. There is European concern about the long-term safety of these crops, Professor Escure noted; is that part of the biosafety protocols? There are a lot of studies going on, Professor Phillips said, and short-term tests will be done. Long-term

tests take longer. The crops will be monitored closely as they are used. An entire regulatory system has been put in place without any known or documented risks.

Professor Phillips explained, in response to a question from Professor Dahlberg, how the seeds go from the laboratory to crops that can be planted. He said that except for one test plot in Louisiana, none of the golden rice has been planted or marketed. They are hoping for approvals from a number of countries, and the use of the golden rice will be highly regulated. Professor Phillips added that the humanitarian clause is not restricted to transgenic crops. The humanitarian issue comes up for any intellectual property with benefits to the developing world where they cannot afford the product due to cost.

Ms. Witson asked what was the meaning of the clause that Professor Phillips read. Does it require the licensee to try to do something? Where does it go? It would be a University policy that would govern any time it wished to license something. Professor Wolf said there is literature on how to make concrete the meaning of the clause.

Is there technology to assess and evaluate crops or medicines, Professor Johnson asked? One hears now, for example, that medicines long thought to be meritorious are now not so meritorious. How is biotechnology tested? In the drug context and the news about pain medications, Professor Wolf said, the controversy has caused renewed questioning of how the FDA does its business. The first question is state of the science to perform evaluation but the second question is whether regulators are actually using the best science to perform evaluations. She said it is her sense that there can be serious barriers to uptake by regulators.

The technology is in its infancy, Professor Phillips said, and is improving every day. As the public raises concerns, scientists work to meet them. With respect to environmental concerns, the National Academy of Science said that the process should not be regulated but the products should be. There is need to monitor genetically-modified crops but the bad scenarios that people envisioned have not come to pass. Most plant geneticists are now saying that the new transgenic varieties are AT LEAST as safe as traditional varieties.

In many cases, Vice President Mulcahy commented, what is accomplished with genetic manipulation simply accelerates what has been done with plant breeding in the past—it now can take one or two years to do what previously took several years. With respect to golden rice, he added, they were not looking to provide cheap golden rice in Africa, but it was simply the goal of the scientists to be sure this nutritious rice was available in Africa. They can see that even if the rice will not be a commercial success, it is still important to make the rice available to particular areas of the world.

Is there definition or consensus on what makes a technology essential, Professor Luby asked? In the agricultural arena, Phillips said that the term "essential" is not used in regard to crop varieties. The general feeling is that if something can be done by conventional means, it probably will be. But one cannot get pro-vitamin A in white rice, so it has to be introduced. This is a "Viagra" question, Professor Luby said: what is essential technology? With some developments, such as golden rice and an anti-HIV drug, there is an obvious humanitarian impact and obligation to seek a way to make it available; with others, there is not such an obvious humanitarian value but possibly considerable income to the University from commercialization in developed countries. If the clause implies an obligation to make each technology developed at the University available for developing countries, this may, for some

technologies, have an impact on the University's ability to license it in developed countries so there is a financial return to the company and the University. The phrasing addresses that problem, Professor Phillips said.

It is not sufficient to endorse a principled statement and assume that all will follow it nationally, Dr. Mulcahy said. There will be some cases that need wider consultation; there could be a group that would advise the University. There is a list of "essential medicines" in the pharmaceutical context, Professor Wolf said. There is the WHO list, Dr. Paller said, but within the United States the definition of basic care is different; the U.S. list of essential medicines would be longer. And how does one deal with the under- and uninsured? They do not have access to the WHO drugs, the ones the WHO says are essential. Licensees would feel much more strongly about the inclusion of such a clause within the U.S. Dr. Mulcahy commented that many times technology is licensed without any guarantee that anything will result; one cannot rely on the WHO list because one does not know what will work.

Why is this issue before the Senate Research Committee, Professor Dahlberg asked? These questions come up after the research is done. Whatever financial agreements are made, he was concerned that the University would be made a scapegoat for untested products being used in the name of helping humanity, which the clause says the University wants. But products should not be released until they meet U.S. standards. What standards should govern U.S. research in developing countries is a big issue, widely recognized, Professor Wolf said. The issue of intellectual property availability and humanitarian access is before the Committee because it arises from research, Professor Balas said. There is no other appropriate place for an expression of opinion about how the University should patent and market its research. The Committee is an advocate for research and for the dissemination of research. This item will be on the agenda again next year, he said. Vice President Mulcahy said his office would have something more concrete for the Committee to look at.

Is there concrete action for the Committee to take, Professor Johnson asked? Or a pathway to concrete action? Professor Balas said that in the past the Committee has been reactive; this is a way to talk more about what will happen in the future. It can also lead to identifying an office or individual in the institution with ongoing responsibility to address these issues to come, such as an associate vice president for research, Dean Green said.

Ms. Witson said the minutes should reflect the apparent consensus of the Committee that the best way to proceed is not for the University to try to negotiate, by itself, a clause in every contract, but should instead look at the issue at a broader level. It is in this position because of a lack of leadership outside the University on issues concerning the health and welfare of citizens, Professor Dahlberg commented; it is difficult not to have a humanitarian motivation but rather than falling on the back of universities and individual organizations it indicates a lack of moral leadership elsewhere in society.

Professor Balas thanked Professors Phillips and Wolf for joining the meeting.

2. Strategic Planning

Professor Balas noted that the strategic planning reports have been in the news. They outline directions the University wants to go in order to meet the Regents' goal of being one of the top three public research universities in the world. There were 31 recommendations in the academic task force report but little mention of research. His question to the President, he said, was about why research was

not a prominent part of the document. The President responded that Board of Regents' action is not needed to improve the research infrastructure; he suggested that this Committee encourage Vice President Mulcahy to take on the issue and identify how the University could move forward to being among the top three.

A related issue, which was raised in the faculty forums, is the disconnect between the budget model discussion and the task force reports. It appears that the budget model discussions will lead to a "purer" form of Incentives for Managed Growth (IMG) so that units will pay for what they get and get what they earn instead of a centralized control system. How does this relate to infrastructure funding?

Vice President Mulcahy said he has had the same questions as Professor Balas. Where do the tactical issues related to the achievement of the strategic planning goal come up? What will happen in the next phase? The first overall goal has been approved (be in the top three) and now the task force reports are out for discussion and the President will decide which recommendations he will accept and forward to the Board of Regents. The Board will not act on research but there are things that need to be done. The time is ripe to advance the issues; his office, this Committee, and the Council of Research Associate Deans must help to address them.

It seems odd, Professor Johnson commented, that the incentives in IMG are all for deans to worry about revenue streams and nothing compels them to worry about research except as it may produce an income stream. There needs to be a dialogue about this or the Vice President for Research will end up like the Dean of Graduate School: a great organization with no money. Depending on the incentives, Dr. Mulcahy observed, that could be difficult to create if the system is one of "you get what you pay for." That creates problems for interdisciplinary research. The budget model has not come up in the planning discussions; he said he did not know what the decision process for the budget model or when a decision would be made. It will, however, have a profound impact on research. Dean Green said it is his understanding that the budget model is farther down the track than the discussion of research infrastructure; there is talk about testing a new budget model in fiscal year 2007 (2006-07). Dr. Mulcahy said he knew there has been a lot of discussion of the budget model and alternatives, but he was not sure the impact of the models on research had been assessed.

The questions involved keeping track of research in budgets, Professor Balas said, and he invited motions that would address the issues that have been raised. The Committee unanimously approved the following two statements:

(1)

The Senate Research Committee calls upon the President and Provost to establish a task force on research infrastructure, as an integrated part of the strategic planning process, and to appoint to the task force the Vice President for Research as well as members of the Senate Research Committee and other knowledgeable groups, and to charge the task force with making recommendations related to research on how the University can achieve the Regents' goal of becoming one of the top public research universities in the world. The Senate Research Committee recommends the Task Force on Research Infrastructure have faculty members as a majority and that it be chaired by a faculty member.

(2)

> The Senate Research Committee requests the President and Provost to include, as soon as possible, the Vice President for Research in discussions of any new budget model the University might adopt, and also requests the President and Provost to insist that any recommendation for a new budget model explicitly include discussion of the impact the new budget model will likely have on the research mission of the University (and, in particular, but not limited to, interdisciplinary research).
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> The Committee also asks the Senate Committee on Finance and Planning to consider this issue as it discusses a new budget model.

Ms. Witson noted that with respect to the second, there is a need to act quickly if in fact the budget model discussions are moving fast; there must discussion of the impact on research before any new model is adopted.

Professor Johnson suggested that the Committee ask the President or Provost why there was not more about research in the task force report. He read through the reports, he said, and also saw nothing on the budget model. The Provost must know what is going on and he should tell the Committee. Professor Balas said that is just a problem with governance; the Committee on Finance and Planning is dealing with the budget model, as is appropriate, but it has not focused on the impact on research. This Committee could not act before it saw the documents; now it has. The President has asked for comments and advice, which he might or might not take.

There has not been as much of an evaluative or advisory role for the Vice President for Research in the past, Dr. Mulcahy said. He repeated his strong feelings that he wishes to establish an academic connection in his office, and said he believed that the President, the Provost, and Executive Associate Vice President Sullivan would welcome the participation of his office. It just has not happened as much up to now. That there could be as much discussion of the budget model without participation of his office suggests that consultation with his office has not been the practice.

Dr. Mulcahy clarified, in response to questions from Professor Escure and Dr. VanDrasek, that when he talks about research infrastructure, he is not only talking about federally-supported research or scientific/medical research.

Much of strategic planning up to now has dealt with structural problems, Dr. Paller said, and has not been full-blown strategic positioning. The only position that has been taken is that the University will be among the top three; there has been nothing on how to get there. Research is not in the task force report because research is not seen as problematic, but that does not mean the Committee should not say what it would take to achieve that goal. Faculty, space, support—none of these are addressed.

Do not most rankings rely on research, Professor Bartels asked? Mostly on money, Dr. Paller said. Dr. Mulcahy said they rely on grant support; the University of Florida study is one of the better ones, because it looks at more than just research dollars, but there are still problems with it. What metrics should one look at? That depends on the activity, and how an institution is ranked depends on what one looks at. The Committee could help to identify meaningful parameters or benchmarks the University could use.

Professor Balas concluded the discussion by saying he hoped that Committee members were offering their opinions about the strategic planning process, whether opposed or in favor. It is important to let the President know how faculty, staff, and students feel. He also noted that faculty may send views to facviews@umn.edu. Professor Orf said that since it appears there will be additional task forces, he would urge that there be more faculty participation. Professor Balas agreed and said that one comment at the faculty forums was that at the best universities, activities are faculty-driven.

3. Secrecy (Openness) in Research

Professor Balas welcomed Professor Ken Heller, chair of the Committee on Social Concerns, and noted that he had distributed before the meeting materials related to procedures for requesting exemptions from the Regents' policy covering secrecy in research, a policy that is expected to be re-named Openness in Research. Dr. VanDrasek suggested the subcommittee that deals with the requests should also be renamed.

This is a draft of procedures and a required form, Professor Balas said. There will be more time for discussion at the next meeting; this was simply intended to get the materials to the Committee members. The issues will also go to the Committee on Social Concerns. The documents have been in the works since last fall and came out of unhappiness about how the process worked last year when there were requests for exemptions from the Regents' policy. The procedures, once approved by this Committee, with advice from the Social Concerns committee, will need to go to the Faculty Senate for approval. They propose changing the current procedure; the requests would go from the subcommittee to this Committee for advice and then to the Vice President for Research (rather than the President) for decision.

Professor Ascerno suggested, on the form that is to be used, the question not be "Will this project affect the educational progress of students working on the project" but instead it should be "HOW will this project. . . ." The same change should be made in the parallel question about the effect on faculty and staff. In both instances, research that has restrictive clauses will have an effect on students, faculty, and staff. Ms. Witson said that the question "To what extent will faculty, staff and students involved in the project be able to publish and discuss the progress and results of their work with individuals not involved in the project working on the project?" is larger; there will also be an effect on students NOT able to work on the project. There could also be an effect on international students and staff, Dean Green added. Dr. Mulcahy recalled that he also had to sign a form affirming that he was not a communist.

Professor Balas noted that if a person requests an exemption, the procedure provides that the request will be turned around in 10 working days. It is important to say that the PI will be offered help. Over the summer, the requests will be handled by email and conference calls. And if they come up during the year, this Committee should hold a special meeting, if needed, Ms. Witson said.

Professor Johnson said there are two questions involved: "What can be done?" and "Who do you have to tell?" Does this procedure address both? Professor Balas said the policy is clear: there are certain things the University will not accept (such as a ban on indicating who the sponsor of the research is). The procedure has nothing to do with what research will be done, it has to do with openness associated with research, Dean Green commented. This policy does not address something like the University declaring it would not do embryonic stem-cell research, Professor Balas said.

The procedure sets out an ambitious timeline, Professor Orf observed. Is it too short or too long? Last summer the Committee had a very short timeline. He said he did not know the right answer but there needs to be time for requests to go through a reasonable set of events so someone in the administration is not forced to say "no" because of procedural problems. That is why the timelines were put in, Professor Balas said; this tells Sponsored Projects Administration that the procedure says it takes 10 days and that if they need something faster, it can't happen. There will be no more of this "we need to know in one day."

Professor Dahlberg noted that two projects were rushed through last summer and were approved. "He asked that there be a broad survey of faculty, students, and staff in the departments where the research from the approved projects was to be conducted proposals were approved to inquire about the impact of the research." Professor Balas agreed.

Dr. VanDrasek asked if this would be for information for the Social Concerns committee. Professor Heller said that any time the University is involved in secret or proprietary research, the entire institution is affected.

Professor Balas thanked Professor Heller for joining the meeting and adjourned it at 3:00.

-- Gary Engstrand

University of Minnesota