SYMPOSIUM ON BIOINFORMATICS AND INTELLECTUAL PROPERTY LAW

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PATENTING AND FINANCING BIOINFORMATICS INVENTIONS

PROFESSOR STACEY DOGAN:

When Professor Michael Meurer first told me about this conference a few months ago, I have to say, I was like one of his stumped students. (*laughter*) What? Bioinformatics? And then I checked Boston University's Web site and realized there is an entire department here devoted to bioinformatics, and I learned something about it. I have the pleasure of introducing our only speakers today who are constrained by case law (*laughter*) and other types of law, our two practicing lawyers. Mitchell Bloom is a partner at Testa, Hurwitz & Thibeault, LLP, the sponsor today, and is a member of the Business Practice Group. He is going to talk to us today about financing issues. Tom Meyers is a partner in the Patent and Intellectual Property practice group, and he will talk to us about patent protection issues.

MITCHELL BLOOM, ESQ.:

Thank you, Stacey. The observation I made when I was looking at the materials that were prepared for this seminar was that my talk really has nothing to do with the rest of the day. So I hope you will bear with me. What I am going to talk about is the question that I get asked every day by entrepreneurs who are looking to start new companies. It is a very interesting question for this conference because bioinformatics, as an emerging space, is going to attract a lot of interest from folks looking to start new companies. It is going to attract a lot of money. It already has, and it is likely to be – because it is not a pure play, it is not a pure life science, it is not a pure information technology play – it is going to be, I think, in the crosshairs of a lot of funding sources, particularly the venture capital community. Basically, that is the discussion I am going to follow up on.

What I am going to cover are a couple of things. One, what are the sources of capital if I am starting a company, and where do I raise this money from? Do I go directly to the venture capital community? Are there other sources

that might make more sense? What are the advantages and disadvantages of other sources of capital, and what are some of the do's and don't's of raising money? Hopefully, you will find that interesting.

The first thing I want to talk about is sources of capital. For an early stage company there are three ways that you can raise money – three sources. First are angel investors and what we refer to in the lingo of the day as FF&F, or friends, family and fools. The angel investor – who is that? Typically, angels are wealthy industry players who have made a lot of money in the space. They have time, hopefully, to nurture your company along, and capital to invest in your business. These days, this is a small community. Unfortunately, angel investment has taken a little bit of a beating over the last couple of months, as you can imagine. Friends, family, and fools, well, I do not think I need to say a lot more about them. They are not what I would consider the best place to raise capital for a number of reasons that we will discuss, but in many instances, particularly for an early stage company that is just an idea, they are the main place to go.

Strategic investors are another source that I think will be particularly interesting for early stage bioinformatics companies because, again, you are going to have a lot of companies coming at this from a number of different areas. You will have companies from information technology, the storage side, the processing power side; and you are going to have companies coming at it from the life sciences side, looking for ways to leverage that information technology. Thus, there are lots of potential companies out there that would be potentially willing investors in companies in this space, and they can be very, very powerful investors, but they also have some drawbacks.

Then, finally, is the venture capital community, the wolf in sheep's clothing. Venture capitalists are clearly attracted to this space, as I mentioned. There are many venture capital life sciences funds whose investors are looking at this space, and there are those that are information technology or Internet funds whose investors are looking at this space, because again, it is a cross-section of a number of different areas. In some ways, they can be the best investors; but of course, people hear horror stories about how "the venture guys took my company and I wish that did not happen." But there are certainly ways to deal with that.

What are some of the advantages and disadvantages of these various groups? Angels. Big advantage: Their deals are simple to do. They are easy deals, and they are quick. Angels do not do a lot of due diligence. They like an idea, and they invest. They do not scour the patent portfolio. It is not something they are going to do. They do not have the time or inclination to do it, generally speaking. They do not ask for fancy terms. Generally, angel investors are not looking for participating preferred with redemption features and weighted average anti-dilution, and the problems that you hear when you talk about the venture capital community. Angels might serve on your board of directors, or they may not. It is usually not a condition for them. Valuation? Basically, you get better valuation. What that means is, you give up less of the company and you get more money, and that is a good thing from

an entrepreneur's perspective. I think that is one of the main reasons that people look to this community at early stages.

What are the disadvantages? Well, there are several. The first major disadvantage is, unlike a venture capital fund, an angel investor is pretty limited in terms of what it can bring to the table. It probably does not have the ability to bring follow-on funding to a company. So while you might raise initial money to kind of get your idea going, a venture capital fund, when they make their initial investment, will typically allocate double that initial investment or perhaps more to support that company in additional fundraising rounds. Angels do not have that capability, so angel investment is very limited. You cannot rely on them; and for example, a company that may have raised angel funding in the last year and is now trying to fund raise in the current environment probably wishes they did not have an angel investor, because they are just not capable of supporting the company. Angel investors can add a lot of value, particularly if they are savvy industry players; but in many cases, I think people are disillusioned by the fact that their angel investor either does not have the time or necessarily the expertise sought to really help build and grow a company. So that tends to be a pretty significant negative.

The conclusion that I reach for angel investment is that for some folks this makes a lot of sense. For a company that is really at an early stage with an idea and maybe the beginnings of a business model or plan, angels are a good source of walking-around money so you can execute on your plan, maybe demonstrate why your business model is persuasive, and hopefully hit some milestones so you can increase your valuation if you want to raise more professional funding.

Strategic investors. Big advantage is they provide instant credibility. Typically they are a big name. They validate your technology. That can be a very, very powerful statement. Like angels, you will generally get a higher valuation from a strategic investor. They are less interested in the financial play. They are much more interested in what can this relationship do for us from a technological, from a marketing or distribution perspective. Another advantage is that they may bring something very valuable to the table in terms of technology. Perhaps it is a license in of core technology. It can be a marketing channel that they will bring to the table. There is a number of different ways that these deals can get structured.

The disadvantage is that they are bureaucratic organizations and it takes a long time to get deals done, and that can be very frustrating. Unlike an angel, they will do due diligence until the cows come home, because they are technically-oriented organizations, and they will spend a lot of time on that. One of the big issues that comes up for a lot of companies is that often a strategic investor will insist on some special rights. It may be a right to buy the company if you ever want to sell it. It may be a right to negotiate to buy the company. It may be a right to a board seat from which they may get access to confidential information that you may not want them to have. These can be very troubling issues, particularly if you go to raise additional funding from the venture capital community, because they have an impact. Giving rights to buy

the company or negotiate to buy the company are particularly troubling because doing so puts a natural ceiling on the valuation that you can get for this company, and a venture investor is not interested in ceilings. They are only interested in their ability to freely liquidate, to get to liquidity on the sale of a company or an IPO. And finally, people need to be cognizant of the neutrality issues. If you are too closely aligned with a strategic partner in an industry, you might lose out on other opportunities; and while their money is green and looks good at the beginning, you need to take a long-term view on those relationships.

The other primary source is the venture capital community, and the big advantage here is that you are dealing with a very sophisticated, experienced financial investor who has been through the drill. They know how to build businesses. They provide access to larger pools of capital, both from their own funds as well as from their "friends," if you will, and they are focused on the drive to liquidity. By that I mean that they are looking at a three to five year horizon where they want to take the company public or they want to sell it. That is what they are in the business of doing. So if that is not what you are in the business of doing, you do not want to deal with a venture capitalist. It is that simple. They are going to be very, very aggressive on valuation. It is a financial transaction. They are going to look for control of the company, they are going to want to have control of the board of directors, and they are going to want to make the key decisions, whether it is spending decisions, budgets, or certainly sale of the company, raising new money. They are going to want control. And quite frankly, venture capital is very, very difficult to attract to an early stage company with, basically, an idea and a business plan. Generally, what they fund are established businesses which are beginning to put together the semblance of a team and an organization that they can take forward. Ultimately, they invest in people, and while technology is nice, most venture capitalists you talk to will say that they invest in management first.

A couple do's and don't's which, for some of you, may not be all that interesting, but for those of you who may want to start a company some day, they may well be. These are some of the more common mistakes that we see people make. The first one is pretty common: people cold calling investors. They basically pick up the phone, they get a list of firms to talk to, but they have no in, no connection. You have all heard the stories of these guys looking at fifty business plans a day, yadda, yadda, and they are true. You need to have an in. You need to have access through a trusted adviser, perhaps a lawyer or accountant, someone who knows the firm and can get you to the top of the pile.

Another common mistake is, people get their list, they find the fifty firms they want to talk to, and they do a mass mailing or they try to contact all of these investors at once. The best case from that scenario is that you get fifty meetings all at once, which is not where you want to be because (a) you will not have the time to do them, and (b) you will not have time to improve on your pitch in each successive meeting because you will be so busy shuttling from one to the other. This is not the way to do it. What you want to do is

make sure you identify the folks who are likely to invest in your space at your stage of company. There are funds that go from the very earliest seed stage to latest stage funds. There are funds that invest purely in life sciences, purely in the Internet, purely in telecom. You do not want to go to a late stage telecom fund with a bioinformatics idea. It is a waste of their time, they will not even look at it, and you will look foolish and lose credibility. That is a point that people sometimes forget.

The other thing people do is that they put together elaborate business plans. And I am not suggesting that you do not need a business plan; you certainly do, for a lot of different reasons. But in terms of getting investor attention, the key is to tease them. Tell them just enough to get them interested so that they will take a meeting, because that is where you have the opportunity to sell yourself. Do not be inflexible to suggestions and criticisms, you need to keep an open mind in the fundraising process. You need to take the feedback you get and turn it into positives. You do not always have to have the right answer, but you have to have a thoughtful answer, and you have to understand and support your assumptions. Those are the issues that people focus on, whether you have been able to think through those issues and can stand up to the challenge.

Another common thing is people offer up a valuation, which is always a mistake, because either it is too high and you get laughed at, or it is too low and you have undercut yourself. You let them set the price and you negotiate from there. Strangely, the worst thing that can happen to a company raising money is, on their first meeting, to get offered a term sheet. You do not know what to do, because suddenly someone is willing to give you money, but you do not know whether it is a good deal. You do not know whether you can get a better valuation, so you need to be very careful in terms of how you manage the process. Do not get hung up on valuation. At early stage companies, you are looking at $6 million, $8 million, $10 million valuations. Another half a million or million dollars, in the long term, is not going to matter. You are talking about long term value. You are talking about businesses that, to attract this type of venture capital, need to be hundreds of millions of dollars in terms of opportunity. They need to be $500 million plus potential companies in a few years, at least at the outset. They do not often turn out that way, but at least at the outset, that is the plan.

Finally, it is very important to be educated about the process. You need to know the lingo. When you are in a meeting and somebody starts talking about a term sheet or preferred stock or weighted average anti-dilution or registration rights. You need to understand those terms so you can respond, understanding what is important and why you do not care about a bunch of these things. You need to know the market, and that is very, very important. Quite frankly, the best way to get educated on that market is really to work with good advisors – your law firm, your accounting firm. Establish a good advisory board of folks you trust who can help you navigate your way through this process.

Thank you. (*applause*)

THOMAS C. MEYERS, ESQ.:

Good morning. My name is Tom Meyers. I am a partner in the patent and intellectual property group at Testa, Hurwitz & Thibeault, and it is a pleasure to be here today. I would like to thank Professor Meurer and his folks, and Michelle Heian and her crew at Testa Hurwitz for putting on what I think is very timely, and what I hope you will find an interesting program today. Bioinformatics really has been the new technology buzzword in high technology over the last six months to a year. You can hardly pick up a magazine in the popular press or scientific literature and not hear something about bioinformatics. In fact, just yesterday one of the secretaries at our firm had Newsweek, and there was a big article on bioinformatics. They got most of it right, despite the fact that I think they had a screen shot of a protein sequence, and they called it the human genome. (*laughter*) But other than that, they had the issues right, and it is just evidence that it is a topic that has captured the popular imagination, and everybody wants to know what we are going to do with all this information that we have accumulated over the past twenty to thirty years. That is bioinformatics defined – the application of computing power to biological data to reveal new patterns, new information below the surface of those data. And my talk today is on how we, as patent lawyers, seek to protect proprietary rights in this area, some of the strategies we are using, what is protectable and what is not, and how we are going about doing it.

I think before we do that, we have to start out a little bit talking about biology because biology has changed a heck of a lot in the last couple of years. It has really become more and more of a quantitative science than it ever used to be, and we think it is going to keep continuing in that direction, becoming more and more quantitative all the time. We believe that strongly enough that we formed within our group, a bioinformatics subgroup that my partner Tom Toronto and I head up. It is seven or eight people who now concentrate on serving bioinformatics companies, putting our heads together, figuring out how we are going to protect proprietary rights in this area, what is different, what is the same, what can we use from some of the old things we have done, and what do we have to do to provide adequate protection for these companies. What we are really looking at is fifty years of accumulated data; and now, what the heck do we do with it?

Biologists are becoming more computer scientists, and computer scientists are having to learn about biology. One commentator recently wrote that if we turned off all the computers, all biology research would grind to a halt. I am not sure I would go that far, but we are seeing more quantitative aspects of biology, and it is resulting in a real change in the way that biologists practice, the way biologists view their profession, and that has resulted in a change in the way we patent lawyers view our profession and the way we view our business. I want to spend a few minutes talking about that because I think that is significant when you go out and think about how you are going to protect proprietary rights in this area.

Traditionally, in patent law, there were two types of patent lawyers. There were the former lab rats, biotechies who talked about DNA and RNA and high throughput screening, and nobody understood what the heck they were talking about. Then, on the other side, there were the engineers and the computer scientists with white shirts, short sleeves and pocket protectors. The two existed in harmony in law firms and did their own thing, but substantively never crossed paths. I would never pick up an electrical engineering or computer science application and try to write it, and similarly my computer science buddies would never pick up one of my biotechnology applications and try to write that. That has really changed now in response primarily to the bioinformatics movement and the fact that biotechnology is becoming more quantitative. We, as patent lawyers, have to respond to that in ways we have not had to respond in the past. Now, what you see, or what you should see in law firms when people write patent applications in bioinformatics, is a collaborative effort between folks who know a little bit about the underlying technology, which is the biology, and folks who know about the algorithms and the software and the ways we protect churning the data. And there are not very many people, Tom Toronto is one of the few exceptions I know, who have degrees in biology and computer science and can sit down and do the whole thing, soup to nuts.

The approach that we have taken at Testa in representing bioinformatics clients is a collaborative approach where we are all learning from each other. We are all trying to find out, how are we going to combine our skill sets to protect the information in this new area, and it has been a challenge. We have learned a lot in the last six to eight months since we formed the group – we have actually been representing clients in the area for a little over a year. Really, if you look at it, we have been representing clients in the area going back five or six years, but we did not call it bioinformatics, we called it something else. So we have been getting patents on x-ray crystallographic structures and algorithms for looking at protein structure based on crystallographic data or sequence data for a long time, but we called it biotechnology back then. Now that we call it bioinformatics, we are looking at it in a different way. We are really adding value that we did not add five years ago because we are bringing the computer science component into the analysis and into the types of claims we write, into the specifications and patent applications that we draft.

So we think we are getting a better product out of that, and I think other law firms and other lawyers are doing the same thing. They are realizing you cannot really sit down by yourself and provide full service representation to bioinformatics clients the way we used to do it. That is the big change from the way that we work point of view, and I would like to spend a few minutes talking about what is protectable out there, and the kinds of things we are trying to do to get protection for clients in this area without giving away any privileged information. So I will talk in very general terms. Much what I am

saying today is in an article in *Nature* article that a few of us put together recently, and it will provide more detail.[1] This is a fifteen-minute talk, distilled down from an hour talk. Tom and I will be putting on a six hour workshop on this topic in July, so needless to say, there is a lot of detail and a lot of specifics that I am not going to have time to get to today. I would welcome questions after the panel, however, and also contact me by e-mail or telephone if you want to get into it in more depth.

Generally, bioinformatics has not created any new statutory subject matter for patents. The only possible exceptions are databases, and we really do not know what the verdict is on those yet, and I think a panel is going to speak specifically on that issue this afternoon. There are database protection acts in Congress right now that are sort of churning their way through and have not gotten very far, there is a European directive on databases,[2] and people have applied for patents on databases, databases containing biological information. To my knowledge, none of those patents have issued yet. We have the benefit of some patent publications through the PCT and the European community that have claims to some of the databases, and we will wait and see what happens. My opinion is, and I can get into this with you in more detail if you want, that the database itself is not statutory subject matter and should not be patented. And since we have already decided, or the courts have already decided, that databases are not, per se, copyright protectable, we have to look to something else, and maybe it is this new area of intellectual property protection that the database statutes will convey. For now, I do not see a lot of database patents issuing.

Now, what people are trying to do to sort of get around that problem is, they are creating fancy databases with meta tags and methods of operation that put a sort of functional utility spin on the database itself. How we create the database, how we use the database, how we manipulate the database, how the database works, and all those things are statutory subject matter, I think, and you see patents issuing for those kinds of technologies even today. So what I want to talk about briefly in the time that I have left are four major areas that I see in bioinformatics. And those are data acquisition and organization, data retrieval and processing, data storage, and most importantly, integration.

I will start at the back and go forward, because I think integration is the single greatest challenge in bioinformatics right now. We have forty or fifty years of data accumulated, especially over the last ten or fifteen years – just this wealth of biological data that comes from thousands of labs, hundreds of different countries, in different formats, captured in different ways. Some of it has been statistically analyzed, and some of it has not. Some of it comes from

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[1] *See* Thomas C. Meyers et al., *Patent Protection for Protein Structures and Databases*, NATURE STRUCTURAL BIOLOGY, Nov. 1, 2000, at 950-52.

[2] *See* EUROPEAN PARLIAMENT COUNCIL, DIRECTIVE 96/9/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 11 MARCH 1996 ON THE LEGAL PROTECTION OF DATABASES, *available at* http://eon.law.harvard.edu/h2o/property/alternatives/directive.html.

blinded studies; some does not. Some of it is controlled; some of it is not. Some of it is on Apple, and some of it is on IBM. And the list goes on. It is all this different data in different formats, and what do we do with that? There is a big premium in bioinformatics of being able to integrate all this data to show patterns that we could not have seen looking at the data by themselves, to recognize what is below the surface of the data, and I think there is going to be a big push – there already is a big push – on methods of integrating data from disparate sources.

You see that in some of the companies that are out there right now, and you see that in some of the patent applications that have been filed. We filed some data integration patent applications, and I know some other people have as well. We have not seen a whole lot of patents issue, and I think that is because it is a relatively new concept, a relatively new field. It wasn't that long ago that people started thinking that we need to think about how we pull all these data sets together to get an informative whole, to recognize patterns that we would not see otherwise. That is really what integration is, pattern recognition, and how are we going to pull this piece and this piece and this piece together to see something that we could not see by looking at the pieces alone. That is certainly statutory subject matter, we are pursuing patents on that, and I think that is going to be the wave of the future in bioinformatics. The companies that can do that are going to be the companies who, I think, will be successful.

Information retrieval and processing. Those by and large are old problems. Those are computer science problems. How do we retrieve information? How do we process it in ways that are going to give us the result that we want? What we have right now is data. What we need is information, and we can use a lot of the old technologies in order to get the information out. There are new technologies as well, but you see less in that area. Storage is another area that has been around for awhile. There are a lot of storage patents out there, and there are companies like IBM and EMC and Storage Networks and others out there who are doing data storage. They have a wealth of intellectual property, and there is a lot of prior art. Nonetheless, bioinformatics implicates a different type of storage. You are talking again about data from disparate sources that you need to bring together and store in a coherent way so it can be accessed to get information. So I think there is room for patents in that area.

Then finally, acquisition and organization. I think that is all part of the whole piece. Data acquisition is what biologists traditionally do, and the organizational component helps in terms of storage and information retrieval and integration. There are some patents in what to do with the flow-through that we are getting that are out there, and there are some patents that we have seen. This is the fourth area that I think is going to be a big intellectual property area moving forward.

What are we looking at then, just in a sort of general sense? Pattern recognition, data integration, structure-function relationships. How do we take all the protein data that we have? How do we take all the genomic data we have, and tell something about the function of those proteins or those genes? How do we turn genes on or turn them off? If somebody has a particular

polymorphic variant such that they are going to be susceptible to a certain disease or resistant to a certain disease, this is why some drugs work on some people and why they do not work on other people and why they kill other people. The ability to take these polymorphic variants – to take differences in protein structure, differences in protein folding, and x-ray crystallographic data, and predict what it means for the system, the state of health of the person, what it means for drug development – is going to be the key to bioinformatics. That is where I think most of the intellectual property is going.

There are a couple of other things I want to mention that I think are going to drive some intellectual property in this area. The development of instrumentation and methods; as we acquire new means of analyzing and integrating data, we are going to need new instruments. There are companies out there doing instrumentation, and I think you are going to see a lot of patents in that area. Standardization and normalization techniques are another big area, in biology generally, but especially in quantitative biology, and I think you will see some patents there.

So what are we looking at in terms of the markets here and what do we see in the future of bioinformatics? Recent estimates are that the industry is growing at about seventeen percent per year, which is pretty good growth. The highest prediction I have seen is about $5 billion in sales by 2005, which is not a whole lot of money if you think about it and compare it to other industries. I think what you are going to see is a lot of consolidation of companies in the bioinformatics space, companies coming together in strategic alliances, acquisitions, and collaborative research, because there is just not going to be enough room for all the players that are in the area today. And what that means in terms of intellectual property is that the companies that have good patent position are going to be the attractive candidates for the buyouts, for the strategic alliances, for the acquisitions, for the collaborations. I think that as for any start-up, there is a real premium on getting a solid strategic patent portfolio. Bioinformatics is no different. I do not think we created new statutory subject matter by creating bioinformatics, but there certainly are some of these issues like integration and acquisition and normalization that are going to provide, I think, a ripe field for harvesting intellectual property rights that are going to help the companies be successful.

PROFESSOR DOGAN:

We have a few minutes for questions before we take a break. Any questions?

QUESTION & ANSWER SESSION

Q: *AUDIENCE*:

Yes, on Tom Meyers's topic, I am wondering if you can speculate a little bit beyond where you are now. You say that you envision lots of new areas for patenting in presentation, storage, retrieval of information. As I understand it, especially in biology, the real need here is for consolidating as much data from all over the world, getting it into a single format that people can then assess it in a uniform, usable way so that they do not have to learn the biology too much in the area of informatics when they are just trying to find biological relationships and so forth. Is there not a danger that whatever it is will add back on as a problem, so that incremental advances in storage and presentation – tens, hundreds of patents sitting around there, people not wanting to pay the license fees, doing things their own way – will come into a sort of Tower of Babel instead of a large, uniform database that scientists can use?

A: *MR. MEYERS*:

I think that is a real possibility, especially with all the companies out there looking at different ways of doing things. One of the things we have noticed is that when companies want to attract venture capital, one of the things they have to do is set themselves apart from everybody else. Nobody wants to give money to somebody who has a lot of competitors. So everyone is sort of looking for their niche and for their special way of doing things, and I think that is a real possibility. I do not know how that is going to play out. We have not seen a lot of patents issued. We have not seen a lot of licenses yet. It is certainly a possibility, and it is also a possibility that one or two or three players will emerge with the dominant technology and that is the way it will go.

Q: *AUDIENCE*:

We have a kind of a model existing with so called business method patents like State Street Bank and this new apparent expansion of patentability, and Congress is reconsidering the question – do you see possibly that we might need some additional legislation at some point?

A: *MR. MEYERS*:

The business methods situation is something different. That was really a new category of patentable subject matter. That is something we had not seen before. I do not think that is going to happen with bioinformatics except maybe in the database context, and we may need database legislation. I will let

the experts talk about that this afternoon, but I do not see any new statutory subject matter being created. People are going to be doing the types of things they have done before in terms of algorithms, data accumulation, crystallographic structures, things like that, but applying it in a new way. I do not know how it is going to come out. Ask me in five years and hopefully I will know the answer, but I do not see the need for new legislation. I think we are fine with what we have because we have a patentable subject matter here, except for the database, and that is what people need to focus on, that we are doing the same things we have done before, but applying them in new ways. Patent lawyers who recognize that are going to be the ones who are going to be successful in getting the more powerful claims.

Q: *AUDIENCE*:

I think you might have created, among other things, some barriers to increasing drugs, increasing productivity, because of licensing issues, and that is apparent in the whole issue of bioinformatics patents. You will not increase the amount of information that you have to license in order to prepare for trials, so that just goes with the territory.

A: *MR. MEYERS*:

That is right. It is true, and people are patenting genes and proteins as well. It creates cost for the downstream pharmaceutical companies.

Q: *AUDIENCE*:

Following up on what Dennis Karjala was asking, Tom, at that time, no new patentable subject matter is necessary in the U.S.,, but what about Europe? What about the rest of the world? If they are reluctant to push very far on software patents, or business method patents, is that a problem you think about with your patent strategy?

A: *MR. MEYERS*:

Yes, we do think about that because Europe is going to be a big player. It is going to be a big market. There is a lot of data in Europe and a lot of companies, bioinformatics companies, coming out of Europe. In fact, it is a significant number compared to the United States. It is something that we think about, and Europe may need to do so. There may be some necessity to push for increased harmonization. Whether we go their way or whether they go our way, I do not know. The business methods issue does not bother me too much. I do not think we are going to see a lot of that in bioinformatics. Software, certainly we see a lot, and databases, I think we are going to see a lot there, you can see big differences between the United States and Europe.

Q: *AUDIENCE*:

With bioinformatics, I never hear the even slightest worry about potential downsides, and yet, the scientific community is starting to wonder about how useful bioinformatics can be at this stage. How aware are you of, or what do you think are the potential downsides or research in this area?

A: *MR. MEYERS*:

That is an excellent question. That is an area that has a lot of potential, we have potential to see things in biology that we have never seen before by looking at the data in different ways. The downside is it is not going to work. It is not going to give us answers we are looking for to these questions. We are not going to be able to tell anything about structure-function relationships, it just does not work that way. But we view it as a real trend towards quantitative biology, which will probably be the wave of the future. Like it or not, there are still going be bench signs, there are still going to be genes discovered, there are still going to be patterns discovered, polymorphic variants and all that. But we really think that the wave of the future is analyzing source data, and that is what companies have been doing over the last two to five years. Now, I do not know. Again, in five years I could tell you what the downsides are, but there is potentially a very big upside.

Q: *AUDIENCE*:

I actually have a question that is for all of you, I think. The companies that have intellectual property rights in bioinformatics, how are they using them? Are we seeing, in this case, in software and business methods that people are using them primarily for cross-licensing agreements and to leverage patent portfolios with other companies and in negotiation with other companies, or are they actually trying to use them affirmatively as exclusive rights?

A: *PROFESSOR. MEURER*:

You know, there are not that many patents yet. (*laughter*) So again, that is something that in the future is going to be a real issue, and my prediction is that it will go the way of licensing and collaboration, and you are not going to see a lot of lawsuits. And similar to the way you do not see a lot of lawsuits among biotechnology startups today – they do not have the money to fund them, they are doing other things – it often pays to collaborate. And there are too many companies in this space right now. I think it is going to have to be narrowed down, and that is going to be done primarily by collaboration and licensing, I think.

Q: *AUDIENC*E:

How will this affect academia? I understand that funding sources do not like to pay royalties. If people do get a lot of patents in this area, will the academic researchers then be hampered in their ability to make use of these new developments?

A: *MR.. MEYERS*:

I think from a practical point of view, only if they want to start companies, only if they want to do something commercial. Most of our companies do not have any interest in going after an academic researcher. If an academic researcher is in that space, they want to get that person onboard and get some collaboration going. So they are not looking at stopping them. It is a possibility, but in the real world we do not see any of that at all.

You know, a lot of this has come out of academic demonstration, and the government is going to have rights in a lot of the inventions that we are talking about today. That will be another interesting avenue for progress. The NIH is going to be, and is, a big player.

Q: *AUDIENCE*:

I have a question about academic use. This raises a range of issues of intellectual property backlash in the health care area. In the academic community and the public health community, there is a huge issue there that they are advocating about right now, the issue of whether that continues and so forth. I wonder if you see a possibility of tension between commercial goals, economic goals, and social goals motivating legislation that would alter this process?

A: *MR. MEYERS*:

Certainly possible. As long as the big pharmaceutical and biotechnology companies have lobbyists in Washington, it is probably not going to happen, realistically, whether it should or not. Like it or not, money drives what is happening with these companies, and as long as people can make money by patenting genes and developing pharmaceuticals on patents, I think they are going to do it, until the government steps in and stops them. I do not see that. I do not have any information that that is going to happen any time soon, at least in the United States, although companies, as you have read recently in the press, have made some concessions in foreign countries where there is a need and there is not money to pay for the drugs. And I think that kind of thing has really caused bad press, but I do not think it is going to have a big effect on the patent system. It certainly has not to date.