

SYMPOSIUM ON BIOINFORMATICS AND INTELLECTUAL PROPERTY LAW

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USE OF PATENTED RESEARCH TOOLS ABROAD: LOOPHOLE OR LIABILITY?

PROFESSOR FRANCES MILLER:

Welcome to this session. My name is Fran Miller, and the speaker for this session is Cynthia Ho from Loyola University Chicago School of Law. She is a graduate of Boston University, but, regrettably, not the School of Law, and Duke University where she went to law school. At Duke, she was a research editor of the *Duke Journal of Comparative and International Law*, and after graduating from law school, she was an associate in the firm of Fish and Neave, one of the largest law firms specializing in intellectual property. She is registered to practice before the U.S. Patent and Trademark Office and has published articles on patent, trademark and copyright. While at Fish and Neave, her practice included intellectual property litigation as well as patent prosecution, trademark and copyright issues. Cynthia also teaches intellectual property and civil procedure, and we are delighted to have her present her paper on international aspects now.

PROFESSOR CYNTHIA HO:

Thank you. First of all, for clarification, I should note that my presentation today actually does not address foreign patent laws, but rather deals with U.S. patent laws that have some sort of extraterritorial application. In particular, I will focus on sections 271(f) and (g) of the U.S. Patent Act,¹ which I think of as the long-lost cousins of direct U.S. infringement. Most of the time, we focus on 271(a), direct infringement,² when everything is done here in the U.S. But, as we are increasingly getting global not only in the size of companies, but in terms of where research is conducted, including research conducted partially in the U.S. and partially abroad, I think that these sections are

¹ 35 U.S.C. §§ 271(f), (g) (2000).

² *Id.* § 271(a).

becoming more and more relevant. I think they are particularly relevant for bioinformatics, and also for other related topics such as business method patents and computer software patents. I think these patents have the same extraterritorial issues because of something that Professor Eisenberg actually mentioned before. The key component of all of these patents is the value of the *information*; the value is not necessarily something that you can physically touch, hold, or see. And, yes, you can hold a piece of paper that has all these A's, C's, G's and T's (i.e., a bioinformatics patent), but it is not that piece of paper that is valuable to you. It is what that stuff on the paper, all those mixed-up letters, actually mean that is important. And, the same thing is true for business method patents and computer software.

I think an international focus is particularly important at this time because companies are struggling to figure out how to stake out their global patent territory. This is becoming more of an issue. Also, I think that some companies are going to try to "get creative," so to speak, while there is no clear law on the application of the extraterritoriality provisions to bioinformatics.

Also, there is another important international aspect, which is, what does this all mean in a post-TRIPS world where, theoretically, everyone (most members of the WTO, which means most countries) has the same minimum patent protection rights. However, even if all countries must follow at least the minimum requirements set forth by TRIPS, different countries interpret these requirements differently, so it is not really the same. Besides, even if you have the same thing patented in two different countries, if one country does not enforce their patents in the same way, it will not be the same. Similarly, even if you have a patent in another country, which would usually enable you to enforce the patent in that country, you may prefer to try to enforce your U.S. patent instead. This may be particularly true when you feel that the activity is based upon substantial contact with the U.S., and that the foreign component is essentially an attempt to do an end-run around the direct infringement law. This theory of liability goes back to the policies that originally prompted the enactment of 271(f) and (g).³

What kind of patents am I talking about? Well, I am talking about actually everything that we have been discussing this morning in terms of patents that can be used as tools in bioinformatics research. Thus, I am talking not just about patents on methods of mining information or patents on computer-readable databases, but also about patents on the underlying genes and gene sequences. As I think Andrew Marks talked about, those gene patents are still very important and relevant in a bioinformatics era; you will need those gene sequences not necessarily as a commercial product but as one step in the *process* towards eventually developing a commercial compound. I am going to touch upon the extraterritorial implications of using all of these types of things.

I think one important aspect is that it may be a little tricky to apply these

³ *Id.* §§ 271(f), (g).

laws, given that they were all enacted pre-1990 and that they are a response to specific, tangible problems. Not that the tangible-intangible distinction is necessarily the litmus test, but, the original laws were created for tangible problems and, when the literal language of the statute becomes ambiguous with respect to new situations, the original intent of the statute becomes more relevant. For example, 271(f), which deals with exports of “all or a substantial portion” of the components of a patented invention, as well as exports of a part of a patented invention, where the part is “especially made” for use in the patented invention and designed to be assembled aboard⁴ – both of these are legislative attempts to prevent a re-occurrence of the *Deepsouth Packing* case (about the patented shrimp casing machine),⁵ and the language is directly tied to those facts. You’ll recall that a manufacturer at one point thought that they had a great way around patent infringement liability. They thought that they would not infringe in the U.S. because they were not technically making, using, selling the product in the U.S. (at least after a federal court imposed an injunction on activity within the U.S.). But, they built all the pieces of the patented invention, and they were shipping the pieces out of the country, including advertising and selling the parts as the same thing as the assembled machine; they were telling consumers they could put this together in ten minutes, as simply as you would put together a doll house. When the case went before the U.S. Supreme Court, the Court said, “Well, it doesn’t look really good, but that is not what the patent laws prohibit, although Congress could do so, so you – the plaintiff – are just out of luck right now.”

Congress did take that signal and enacted 271(f), but the problem with that section for today is that it talks about contributing, essentially, to overseas “infringement,” i.e., activity that would constitute infringement if it were performed in the U.S. The law refers to exporting a “substantial part” of a patented invention.⁶ So, the first question then becomes, whether a patented invention includes those in the area of bioinformatics. As we keep talking about, the patents for bioinformatics are really going to vary. We have a lot of different patents at which to look. The first issue is what is the product that would be included under 271(f)? Although there are some cases that say 271(f) is not limited to mechanical products, I have not seen any cases that have applied it to bioinformatics patents in particular. There is a little bit of literature – actually, Dan Burk wrote a very good early article on the application potentially of 271(f) and (g) to computer software and networks, suggesting that the courts could really consider all of these activities within the

⁴ *See id.* § 271(f).

⁵ *Deepsouth Packing Co., Inc. v. Laitram Corp.*, 406 U.S. 518 (1972).

⁶ 35 U.S.C. § 271(f)(1) (2000) (referring to the supply of “all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside the United States in a manner that would infringe the patent if such combination occurred within the United States, . . .”).

current laws.⁷ The courts, though, have not taken him up on that and they have actually been very, very narrow and restrictive in their interpretations of what is a product, for the most part.

So, assuming that patented inventions under 271(f) can include bioinformatics inventions, what are the additional issues for application of 271(f) to patented research tools? We said that it does apply to “components” such as the pieces of a mechanical product. But, what is a “component” “of a bioinformatics patent? If you have a patent on a gene sequence, what – if any – are the components? Can you think of a gene sequence as anything but one thing? And, it is important to think about this question because, in one case, the court said that if you have a patent on a design, if you have a design for a shoe sole, for example, there are no components.⁸ You are just talking about one shoe sole. It is one complete thing with no components, so tough luck. There is nothing you can do about it. In a way, I could think of gene patents as being analogous because there are no clear separate components to it.

Let’s consider another example. If you told someone how to make a patented research tool, or even instructed them to look at a patent, would that be the equivalent of exporting all the parts for the shrimp machine or for an infringing doll house? In other words, regardless of the technology, is it all the same thing basically if you enable someone to infringe abroad?

In addition, let us consider a database example where the method of using databases, i.e. searching for genomes or other research material on a database, is patented. If you are searching overseas, with the database either in the U.S. or abroad and you have the results of the searching going back and forth, is there a product exported within 271(f)? I do not think there is any clear case law.

I do think that this is an area that is going to be litigated by the parties who are going to be arguing one way or the other, depending on who has the patent and what they want to do. I definitely think it is something we should start to think about and, perhaps consider legislation.

A trickier issue, or at least a different one than 271(f), is the application of 271(g), which deals with imports of patented *processes*.⁹ Again, we are dealing with the same type of research tool patents, but now we are dealing with the *products* of the *patented processes* that are imported. What kind of things are we talking about? Well, we could have the end result of the data mining or we could have imported an actual commercial product after you do a lot of testing on gene sequences discovered through a patented process. We have the same sort of problem as we did in the 271(f) inquiry – the initial question is, what is the product that is made by the patented process? Although a “product” that is “made by a process patented” may sound

⁷ Dan Burk, *Patents in Cyberspace: Territoriality and Infringement on Global Computer Networks*, 68 TUL. L. REV. 1 (1993).

⁸ *Aerogroup v. Marlboro Footworks*, 935 F. Supp. 220 (S.D.N.Y. 1997).

⁹ See 35 U.S.C. § 271(g).

reasonably clear,¹⁰ the case law is anything but clear, and the legislative history is even worse. One of the Federal Circuit cases discussing 271(g) recently said something like, “Well, if you look at the legislative history, there is something in it for everyone.”¹¹ The cases and legislative history do not exactly enlighten one’s reading of the statute.

The issue about whether a product is made by a patented process is likely to be difficult for courts to resolve in the bioinformatics scenario since they have had difficulty in areas of much simpler complexity. Consider, for example, a patented process of creating an intermediate compound that then gets changed almost directly into the end-commercial product. Even in those types of cases, the courts have not been consistent. Some courts say, “Well, if you have several different steps that change your intermediate to the final product and in doing that, you change the chemical composition and/or the utility, that is a substantial change and it is not covered.” Courts say this even though this scenario looks like it is the same policy that this statute was intended to cover.

You are not supposed to be infringing under 271(g) if there is a “material change” or if your end-product becomes a “trivial and non-essential component” in another product,¹² but it is really unclear what that means. The case law does not really give clear guidance. The case law out there, for the most part, pertains to mechanical products or sort of old-age biotech, such as basic insertion of DNA into plasmids; in addition, that is all Congress was really thinking about at the time it enacted 271(g), also referred to as “process patent” legislation. There was a perceived loophole for U.S. patent owners because there were generic companies who, basically, could read the process patent like a recipe, make it abroad, and ship the product back into the U.S. where it would undercut the price of the original patent owner-manufacturer. Today, it looks like you could maybe do the same type of thing with bioinformatics, i.e., work around the literal patent laws and deprive the patent owner of the usual patent prices; but it gets trickier because the subject matter involved is several times removed now from the patented product or process.

As we keep hearing, bioinformatics is just one stage in the process of getting to the end-product on which you are actually hoping to make commercial sales. If you get certain data from a patented bioinformatics method and you send that data back to the U.S., for example, in an e-mail, is the data in that e-mail a *product* that is made by the patented process? The content of the e-mail seems like information, although we now know that information-like things, such as bioinformatics, may be patented. In any event, I am not sure labeling the content as information determines whether it is within the statute. In addition,

¹⁰ 35 U.S.C. § 271(g) (imposing liability on those who import a “product which is made by a process patented in the United States . . .”).

¹¹ *Eli Lilly v. American Cyanamid*, 82 F.3d. 1568, 1581 (Fed. Cir. 1996) (Radar, J. concurring).

¹² 35 U.S.C. 271(g) (“A product which is made by a patented process will, for purposes of this title, not be considered to be so made after (1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product.”).

I'm doubtful of whether courts would be willing to include information products as within the scope of the statute. The courts seem to be anxious not to veer from the statutory language, though it is difficult to avoid doing so when you do not really know what that language means.

Here's a fuller scenario to contemplate. Say you did preliminary screening abroad with a patented U.S. process. Assume that there is no patent liability in that country so the screening activity itself doesn't pose a problem. Then, from that screening, imagine you came up with ten possible compounds on which you then did extensive further testing and sent the research back indicating that two compounds you researched after that preliminary screen had good bio-availability and high potential. Well, that activity, i.e., the e-mail about two compounds, does not sound like it would constitute a direct product anymore because there are all these other efforts that are incorporated outside the patented process used for an initial screening.

Again, the statute is not very clear, and it looks like what the courts always tend to do is cite the legislative history and they try to apply it. In the end, they sort of throw their hands up in the air and say, "Well, we do not really know what weight to give the legislative history because there is all this different material that fails to elucidate the statute, so we are just not going to do anything." To show you what the legislature had in mind, I will take a couple of examples they provided and try to analogize them to bioinformatics to show that the correlation, if any, is tenuous at best.

One example from legislature history that courts refer to is the Senate Report.¹³ This is supposed to highlight what should and should not be within 271(g). One pertinent example is a patented process for extracting minerals from the earth. The Senate Report says clearly that if you just extract the minerals, the subject matter of the patent is the process for getting the minerals, but sending minerals mined by that process abroad back to the U.S. shall be an act of infringement. If you extract the minerals and then refine them and add them to some car which eventually gets imported, however, the imported car falls outside the scope of 271(g) having incorporated so much else into the end product. In other words, the minerals that resulted from the patented mining process are such a small part of the imported car, that the activity is outside the scope of 271(g).

If you think about how that could be analogous to the bioinformatics area, it is not quite applicable. If you have a patented process for mining a genomic database, you could import the information back, as I talked about, but it is not quite the same because now we are not talking about a physical product that you get. You are talking about information. I think there is at least some tension about whether or not we should protect that. Also, in terms of down-the-line things you could do with the information you get from protected genomic databases, if you conduct further testing and only use subsequent information, it is unclear whether that would run afoul of the statute. We can

¹³ S. 1172, 106th Cong. (1999).

try to make these broad analogies, but nothing really fits very well. That is really important, in my mind, because it looks like courts have been hesitant to find infringement under 271(g). There are a number of published opinions finding non-infringement on summary judgment, but the only times you see infringement under 271(g) is where the facts mirror closely a scenario set forth in the legislative history.

For example, the legislative history talks about having a gene and putting it in a plasmid, still being covered under 271(g). Remarkably, a court faced with the same facts found infringement under 271(g). But, if you have something other than a gene in a plasmid, the courts become very uncertain in application of the statute.

Since the statute and legislative history are not that clear, we have a fundamental problem with what the statute means, and the peculiar problem in the international context is the TRIPS issue for extraterritorial provisions. What I mean by the "TRIPS issue" is not the provision of minimum patent protection. What I am really talking about is that TRIPS has a non-discrimination requirement that is very different from GATT. Unlike GATT, which just says you cannot discriminate between foreign and national products, TRIPS also says that once you decide to provide patent protection, you must also provide enforcement for all patented products as well; at least, that is how I would read the non-infringement requirement of TRIPS.

Thus, if we have a statute that arguably only provides extraterritorial protection for these mechanical, low-tech, old world biotech patents, but not the more recent patents, I see that as a potential TRIPS problem because of a failure to provide equal patent enforcement rights. In addition, as we know from things like the "Banana Wars," TRIPS problems can become big, global affairs. I do not think anyone has raised this yet as a problem, but I also do not think we should wait for it to become such a problem.

Obviously, the TRIPS issue could be a whole discussion, in and of itself, but that is one reason why I think for bioinformatics patents, as well as all these other patents that do not fit very neatly into 271(f) and (g), such as business methods etc., should be given further attention. This is a very complex area with lots of issues, but I wanted to at least highlight the existence of a potential TRIPS "trap." It looks like there may be some loopholes under the current law and that unless we fix those loopholes, we might be facing not only troubled domestic courts, but also a global problem with a potential TRIPS issue in the near future.

Thank you. (*applause*)

PROFESSOR MILLER:

We have two superbly-qualified commentators on Professor Ho's presentation and rather than give you the laundry list of what their credentials are, we will take their current affiliations and assume that means all that goes with it. Kerry Flynn is the Chief Intellectual Property Counsel for Cubist Pharmaceuticals and Michael Gollin is a partner at Venable.

KERRY FLYNN, ESQ.:

Hello. I am going to start off, actually, by throwing out a couple of thoughts, one of which is that I do not think there is a problem with TRIPS, so I have a little point of disagreement. The reason that I do not see this as a big problem is that I think that patents are enforced in the same way, regardless of the subject matter of the invention. Going back to the original statutory subject matter, looking at 35 U.S.C. § 101, if someone invents a new and useful process, machine, manufacture, or composition of matter, then it will fall within the scope of the laws.

“Information” is not in any of those categories. Therefore, “information” should not be thrown into the discussion in that way. Information is very, very valuable as Professor Ho said. It is the key that unlocks the value within a lot of these bioinformatics-type technologies. The fact that it is very valuable, however, does not make it patentable and does not make it something to which access should be exclusive to one party. Information is meant to be shared by everyone, and I think the results of informatics should be shared.

One of the other things that always strikes me when we have these discussions is the importance of careful claim drafting. When you are writing your patent application, you can frequently avoid many of these issues. If you draft your claims so that you are not claiming just the steps of a process, if you put in product-by-process claims, then you can avoid a lot of these issues. So much of it comes back to careful drafting at stage one and envisioning what the scope of your invention is to do that properly.

With that, I will pass it on over.

MICHAEL GOLLIN, ESQ.:

Thank you, Cynthia, for your presentation. Thanks to my former professor, Fran Miller, for the invitation. I cannot resist pointing out the fact that it is twenty years ago, this year, when I entered this law school, and it is seventeen years ago when I issued forth with a J.D. Since we are bashing patents or at least questioning what their value is, I can tell you, with absolute certainty, that if I were a patent, I would be expiring this year, but my law degree just keeps on going without expiring, like a trademark. So, if you are trying to value a law degree versus a patent, I think the choice is clear.

Seriously, though, the process of synthesizing bioinformatics, patent law, and international aspects of both into a comprehensive analysis is nearly overwhelming. As I said to Cynthia, I thought, at first, she was going to be dealing with foreign laws. However, I was glad my colleagues did not deal with them in any detail here. My analogy is that practicing patent law in the United States is like learning to sail inside a harbor, which is hard enough, learning all the ropes and how to tack and turn. When you deal with international principles, it is like leaving the harbor and going out into the open

sea. The policies and laws are quite different, and much more challenging.

I have a few practical questions as a practitioner that come out of this very interesting topic of the extraterritoriality of U.S. patent law and, in particular, as it relates to this type of patent in bioinformatics. And I use that term, "this type" fairly loosely because we are still wrestling with what type of patent they are.

As a practitioner, I think first in terms of freedom to operate on behalf of either a real or a fictitious client. That brings up the image of, say, the European Molecular Biology Laboratory or a foreign company, Novartis, for instance, which is accessing a database, or building a database, or is otherwise active in bioinformatics. The question is whether any of those activities would infringe U.S. patent laws? In that context, the need for caution and conservative application of these statutes becomes clear because if you start bringing infringement actions against foreign entities who may have tenuous associations with the United States, there are many different issues that can arise.

From a practical point of view, though, what is it really that bioinformatics patent claims would cover? Let me just talk about a few patent issues. If you search for the term "bioinformatics" on the U.S. patent application publications database, which started on March 15th, nothing comes up. If you put in the same search term on the patent database however, you get 125 matches. They include a couple of patents that issued in February to Affymetrix, which is a company that makes biochips for analyzing gene-expression data. One is the Holy Grail type of claim for a data structure, about which we have been talking, U.S. 6,188,783. It starts off, "A computer-readable storage medium, having stored thereon a relational database comprising. . . ." and then it goes on "a probe table," which are the probes they use for searching, a "sequence item table," which is made of the sequences that they pulled out, and "wherein there is a many to many relationship between the probes and the sequences." Really, all they are saying is that they have a database of the results of using their probe. That is, in effect, the product of using an Affymetrix gene chip.

The stark question is whether such a data structure claim is valid? One of my computer software colleagues, who is a former examiner and has been working with these guidelines for five years said, "Of course, that is not patentable." I found the Affymetrix claim and showed it to him, and he said, "Congratulations to the attorney who got that through."

Whether the data structure claim is enforceable or not is another question, but the fact is, there it is. Affymetrix is extremely aggressive in asserting its rights, having the most draconian reach-through terms and grant-backs of inventions made relating to their chips with which I have ever had to deal. Thus, it now becomes a real issue as to whether Affymetrix could assert a claim against a company such as Novartis, or a government agency in a foreign country, which makes its own gene chip for its own research and uses this type of database structure and, in turn, makes the information obtained therefrom available via the Internet to researchers around the world, perhaps without even charging a fee for it. Maybe it is a public database made available to try

to provide incentives for people to share information and to do research. An enforcement of that patent claim, actually, could be very destructive.

There may be some safety valves, however. I wanted to talk just for a moment about the consequences of a literal act of infringement of a product like that. Notice, of course, that if you download, if you hit that web page and look at that data, if you access a portion of that database, you are putting that data on a computer-readable storage medium on your own computer. So you now have that data in the United States and you have imported it or you have used it, or whatever the rubric may be. The question arises, however: So what? What are the remedies for that infringement? The remedies can be two, really: injunction or damages. Now, injunction could be a serious remedy. There was such a remedy with obscene information on CompuServe in Germany where there was an injunction against the web carrier to block that information. In theory, one can imagine the customs service doing an anti-importation or a 271(c) action,¹⁴ or something like that to prevent the entry into the United States of that type of medium.

On the damages side, I am not so sure there is a problem because, in many cases, the damages will be nil. That is, there is not going to be any profit to disgorge, and, if the information is being provided free by a public database, it is hard to see what the reasonable royalties would be, especially if there is competing information, in which case no one would pay a penny for it anyway. While the damages side may not be of such great concern, in other cases it might be. And we still have to think about the screwy international aspects of injunctive relief. International politics and the TRIPS agreement and the way that such injunctions would dovetail with foreign patent law – this goes back to the international complexity I was afraid of, the problem of sailing in the open ocean. Most other countries are nowhere near as permissive in patenting software and, certainly, information-related inventions as compared to the United States. Thus, I think you would easily have a scenario in which activity that is perfectly legitimate under the Swiss or German or Indian patent laws is considered to be an act of infringement in the United States. So that does create an imbalance which could rise to become significant.

One final thing to discuss is another form of computer-readable media, but it is a tangible medium. This is the sequence of the human genome, published as a *Science* magazine fold-out poster on February 16, 2001. It is an impressive presentation of data. In fact, you need a magnifying glass to see anything on it. This poster, too, may be considered a bioinformatics product. However, you could not patent it because it is printed matter. That takes us back full-circle to the issue of patentability.

What Kerry was saying, which I agree with, is that a lot of these issues can be resolved by good patent drafting. The lawyers for Affymetrix, I submit, did an excellent job of patent claim drafting because a patent attorney's job is to

¹⁴ See 35 U.S.C. § 271(c) (2000) (describing importation of components of patented matter as contributory infringement).

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get, as aggressively as possible, as many claims as possible. As we heard before, if the data structure claim we discussed fails, they have other ones, too. It is inevitable that we will see more of these claims issues, and they will probably be litigated. I suppose the issue of significance of the extraterritorial enforceability depends a lot on the types of patents that come out of the U.S. Patent and Trademark Office.

I will stop there and thank you. (*applause*)

PROFESSOR MILLER:

I cannot resist saying that this morning I was actually speaking at another conference on the information side, but on the health care side of things. The question was the new privacy regulations under HIPPA, which some of you may or may not be familiar with. And, you know, “Le plus en change, le plus est le meme chose.” They are the same issues, and the question there was: When you disclose information to an authorized party, get your informed consent, and, then, they de-identify it and strip it and move it down? It goes down to the chain in different forms. The question is, where do you draw lines? How do you enforce rules, etc.? But it was the same kind of a problem in just a completely different kind of a context. I feel as though I am leaning off the other side of the mushroom, you know, a few hours later after having gone to that.

QUESTION & ANSWER SESSION

Questions from the audience on this. Yes?

Q: AUDIENCE:

This is for any of the panelists to answer. It seems from the case law that patent misuse doctrine is not viable. Our clients made the observation a couple of times that the more outrageous patent system gets, the more activity we see in sort of around the misuse and antitrust side. I actually have a student who is writing about some of this. I wonder if we have these claims like the Affymetrix claim and the claims that Professor Eisenberg talked about, to the extent you think any such claims are outrageous, whether we might see a reinvigoration of patent misuse doctrine to deal with some of these patent reach-through clauses. Is there a concern that we may otherwise block downstream innovation by virtue of having the information tied up in very creative kinds of ways?

A: MS. FLYNN:

I have a couple of thoughts on that, and I start out by saying that two parties negotiating at arms' length can agree to whatever business arrangement they want. If it includes reach-through royalties, that is fine as long as there is no

undue pressure. What I think is the more interesting question that everybody talks about is how patenting and research tools reflect poorly on the patent system. Really, this is nothing new. If you go back to the early days of genetic engineering, you know, the old Genentech patents, you look at those today and you think, "Oh, my gosh, those are so broad. How could anybody claim that? It covers everything." At the time, however, it was new and it was novel and it was patentable. That became a very freely-available patent, and everybody took a license to it, rather than challenging it in most cases because the royalty, which was a reach-through royalty, was so low. I think they were licensing it to anybody for about 0.5 percent royalty. So the question really is, the economics that are associated with the patented research tool, and to the extent people placed a value on that, it is not coming from the Patent Office, it is coming from the parties who are negotiating. If industry did not enter into agreements with Affymetrix or with the other companies who do that sort of technology for those prices, this would not be an issue. Clearly, they value that technology or value the composition of the information that these companies have put together and the ease with which they can maneuver through these databases, there is something people are seeing of value there. I think it is not the patent system that needs to be corrected. I think it is the economics that parties are willing to pay in these negotiations.

A: MR. GOLLIN:

Following up on that, I agree that as long as the parties are willing to make these deals. With the Affymetrix example, the client says, "Oh, okay. So anything I invent using their equipment belongs to them. Fine. I will not do any invention there. I will just do my screening, and I will not have to face that problem." The other point is that you can get a reach-through, but the prudent thing is for the licensor to give a choice. "You can pay me a million dollars. Or you can pay me ten thousand dollars and a current 5 percent royalty." Then, it becomes a matter of choice.

I also wanted to touch on the topic of the safety valves and where the friction, where people are elbowing each other, how they accommodate, and how do they release pressure that may build up from inappropriate acts or acts that are perceived as inappropriate. There is a very nice paper that was posted by Commissioner Dickinson just before he stepped down for the new administration in Washington, on patent pooling, which I commend to anybody who is interested in this issue of research exemptions and blocking and so on. They did a very nice research, a very nice job of researching historical examples of situations where patents have been pooled in various areas. I think there are a lot of areas where there are a lot of disaggregated patents which were put into a pooling arrangement, and it really facilitated research and helped standardize, and everyone walked away smiling. The report is a response to the public outcry about gene patenting and research-tool patenting, and this was, I think, Dickinson's parting gift to try to mollify some of that and find a practical solution. Having looked through that, I think it is

viable, but from a corporate cooperation point of view, I think it is tricky and difficult to do that in the absence of, say, litigation or maybe government intervention.

A: *PROFESSOR HO:*

I do want to follow up, actually, on the issue of misuse. I was not thinking so much patent misuse because I felt like the case law is so established that courts would perhaps be resistant to use the doctrine. I was thinking more in light of things like the Rifkin-Newman patent that is being used in an attempt to block a whole area of scientific research by getting a patent.¹⁵ Maybe courts would do something different, which would be the equivalent, and say, "Well, we are just not going to issue an injunction because this is ridiculous. You have this patent just to prevent people from continuing research. You are not doing anything to help anyone. You just want to stop everything." I would think, or hope, that maybe courts would find sort of a public health exception not to issue injunctions in those types of cases. It would be analogous to what we think about patent misuse, establishing new grounds for situations in which the parties are not in equal bargaining positions and cannot really contract properly. It is fine when everyone has equal bargaining power, but I do not think that is always the case.

Q: *AUDIENCE (PROFESSOR KARJALA):*

I would just amplify that last point. First, this notion of a no injunction regime or, at least, encouraging courts not to issue injunctions essentially, it is a form of compulsory licensing so that the court decides the amount of royalty. Many of us in the copyright area have been arguing for a long time that the courts really ought to be taking this more seriously. The Supreme Court hinted toward this in the *2 Live Crew* case,¹⁶ but compulsory licensing is, really, anathema to the copyright lawyer. We really take a serious risk of personal injury as copyright lawyers. (*laughter*) Yet I think it is quite important as intellectual property rights and copyright-like rights move into functional areas, scientific areas, that we have to start thinking out loud and actually discuss the possibility that we just will not stop, we will not stop it. People will have to pay some sort of a fair royalty. I think that is an area where all of us have to do a lot more thinking.

I would like to ask Michael one question. What is the fundamental objection to the Affymetrix patenting? I presume if they invented the whole

¹⁵ Cynthia Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J. L. & POLICY 247, 247-53 (2000) (describing the Rifkin-Neuman patent application issue in more detail, as well as whether it raises a morality issue for patentability).

¹⁶ See *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569 (1994).

thing, there is nothing wrong with adding another very useful kind of a device. What is the objection to that patent?

A: *MR. GOLLIN:*

Well, that is a good question. If you look at the claim, I am not sure whether it is new or not, so there is an issue of novelty validity which we should not get into, but, assuming that it is invented, I do not really have, as a biotechnology-based person, a fundamental problem with that. It just runs contrary to established doctrine in the Patent and Trademark Office, and I do not really have the same level of concern about the access to the information because there, it is not a DNA sequence that is being patented in the way that a variety of data claims are made. Some of you called that a “data structure,” which one may patent.

Q: *AUDIENCE (PROFESSOR KARJALA):*

That is not even contrary.

A: *MR. GOLLIN:*

Right, so I do not find it offensive, assuming it is new, but it does raise this issue of the extraterritoriality enforcement. If somebody is practicing the gist of the invention overseas, and all we are doing is looking at it on their web site, on their server, overseas, that constitutes an infringement act of the United States.

PROFESSOR MILLER:

Okay, another question, in the back.

Q: *AUDIENCE (SCOTT BROWN):*

I just have one comment on the patent pooling concept in speaking from an industry perspective at Millennium Pharmaceuticals. I do not [know] the traditional models are working here. The traditional models have had all those references and paper from the Patent Office. It was a situation where the industry was all making the same thing. Everyone is making DVD players, everyone is making VCRs, everyone is making whatever electronic device, but most of them are electronic devices. That is not true in the pharmaceutical industry. Everyone is not making the drug to target the same disorder. Some are making a; some are making b; some are making an x, but there is not one central compendium of IP that everybody needs to practice the technology. It is, “I do not want this small shop. You are gonna want that small shop.” And doing the balancing, there is more of an equality of what people need, and often people are contributing which makes the pooling much, much easier to

handle. Here, where people could be taking different pieces, it is difficult for this kind of structure, and also political reality that withholds genomics patents on these targets. There are a handful of five, six, seven, eight, a dozen players who end up holding the vast majority of the information that is already on the patent. I think, unfortunately, in some respects, those traditional models of pooling do not apply very well to this genomics area. I would love it if they did. I just do not think they will.

A: *MR. GOLLIN*:

I think it is a different scenario with drugs and a database. If you have a pool on the bioinformatics databases and methods of manipulating databases, so that people could have a transparent access to GenBank, etc.

Q: *AUDIENCE (MR. BROWN)*:

It would work better in that setting. It would work better with commonality of use, but that paper suggested applying it even to target patents, to gene banks. It just, it does not work for me.

Q: *AUDIENCE (PROFESSOR KARJALA)*:

I just had a quick comment. I guess if you start selling these things, you run into the issue of exhausting your patent rights, (a), and (b) if it happens overseas, you get back to the issue of imports. It can get very, very complicated once you start selling these things.

Q: *PROFESSOR MILLER*:

Any rejoinder?

A: *MS. FLYNN*:

Just the one thought I was having is that people talk about selling their research tools, and I heard comments earlier about people being frustrated in trying to get reach-through royalties. But if you go back to the patent law, what can you do with a research tool patent? If you sell it, sell the tool to individuals, what are your damages when you go to court? You cannot get a reasonable royalty because you are not asking for royalties, so it is very hard to settle now that you are looking at lost profits. Thus, many of companies I know that are doing research-tool licensing are asking for the reach-through royalty for the purpose of having a damages standard if they ever have to enforce the patent against a third party, even if it is a minuscule royalty.