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TO: SACGHS

FROM: Brian R. Stanton, Ph.D.

RE: Minority Report

DATE: October 8, 2009

Mr. Chairman and honorable members of the Committee , I submit this letter of dissenting opinion regarding the Final Draft of the Report of the Task Force (TF) on IP and Genetic Testing only with the greatest of forethought and respect to the its members. (The Report was transmitted to me on September 21, 2009 and was entitled “SACGHS Gene Patent Report_Final Draft_9-17-09.doc” (the Report).)

My name is Brian Stanton, I am an ad hoc member of the Task Force submitting its majority report to the SACGHS, and I have been directly involved in the legal, technical, policy, and social debates on gene patenting and genetic testing for almost twenty (20) years. I was one of the principle authors of the US Patent and Trademark Office’s 2001 Utility Examination Guidelines, and I am an acknowledged supporter of broad intellectual property protection as a means of promoting innovation.

It is my opinion as a member of the public and the Task Force, that the Report is fundamentally flawed and if the suggestions contained within it were implemented there would be significant harm to medical innovation.

After years of study and effort, the data demonstrates no evidence that intellectual property (IP) laws or licensing practices are the cause of general harm, a lack of technology development, or any systemic lack of public access to genetic testing. Rather than presenting this finding, the Report proposes that this is not the case and that the evidence suggests that further effort is merited.

Therefore, I urge the full SACGHS do one of three things:

1. halt the current line of inquiry.
2. return the current draft report to the Task Force for revision, further study, and reconsideration, or
3. disband the Task Force and convene a new task force with a balanced membership of Intellectual Property, Industry, Academic, and medical experts where the number of representatives reflects the distribution of input from interested parties based on the public comments on the study submitted to the Task Force.

Unfortunately, the Report is ill-conceived and fatally flawed to such an extent that it serves no purpose. Further, the suggestions contained in the Report are inconsistent with the evidence obtained, redundant to other IP management efforts, and fail to identify any endemic problems or issues. I therefore formally dissent from its content, conclusions, and suggestions.

The Report can be generally separated into two sections — the Body and the Report Recommendations, each of which are discussed below. The Report provides no valid evidence of systemic or endemic problems in the IP system. Those issues that are identified in the Report have either self-corrected or are otherwise under review. Objective review of the empirical data contained in the Report clearly indicates that further action is not merited at this time.

Report Body

The Body of the Report is confused, illogical, presented in a biased manner, and fails to support the Recommendations. A review of the Body of the Report reveals:

1. The scope of the report and the scope of the assignment are misaligned, and the data has been misinterpreted.
2. The report is based upon flawed assumptions.
3. The report is presented in a biased manner.
4. The opinions, conclusions, and suggestions of the Report extend beyond the scope of the Task Force mandate.
5. The report contains inconsistent findings and flawed logic.
6. The report fails to present and represent the input of public comments in a proportional and fair manner.
7. The report fails to address and study alternative means of achieving an appropriate balance between the incentives provided by the IP system and the public interest.
8. The report fails to explore the benefits of the current system.
9. The report is written in a manner that confounds the reader and therefore, cannot be relied upon to aid in decision making.

The scope of study that was carefully considered and agreed upon by the TF membership is reflected in the title, "…Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests". Also, the records of TF discussions reflect that the TF agreed to attempt to address the issue in a narrow and non-biased fashion. My notes reflect that the consensus mission was to:

> *"determine whether IP affected access to genetic testing, and if so, what that effect was."*

That is, as I understood the project, the purpose was to define any intersection between IP and access and determine, to the extent possible, how that intersection affected patient access.

The second paragraph of the Report indicates divergence from this agreed-upon scope. Specifically, the Report states, beginning on line 32, that (emphasis added):

> *"the Committee set out to detect any evidence of the benefits of patents and licensing practices in promoting the development of genetic tests and any evidence of the costs of patents and licensing practices: particularly, whether patents and licensing practices have limited the quality of known genetic tests, the availability of these tests to patients at reasonable prices, and the ability of clinical, research, and commercial communities to develop new genetic tests."*

These are two very different mission parameters.

Regardless of phrasing, two things are abundantly clear. First, at least this member of the TF was viewing the task differently from that described in the report. Second, the purpose set forth in the Report is not a recognized TF consensus.

In addition, the phrasing used in the Report indicates a study on the utility of patents and licenses per se whereas the Report title and the record of Task Force discussions indicates a more balanced approach to a complex problem. The very statement of purpose in the second paragraph of the Report sets the stage for investigator bias.

On line 391, the Report states:

> *"The case studies also found that those with patents did choose to develop genetic tests, but the case studies generally did not address whether these patents attracted investment or made patent holders willing to invest to develop a test."*

If this is the case, why are statutory changes needed and how did the Report author come to the following

conclusion (see lines 412-416, emphasis in original)?

> *"Patents do not serve as powerful incentives for genetics research in the diagnostic arena, disclosure of gene-disease associations, or development of genetic tests."*

What is the basis for this conclusion?

If those with patents chose to develop genetic tests, why is a major observation that patents do not serve as a "powerful incentive"? Is the intent to say that patents are not a strong incentive? If so, on what is such a conclusion based? In particular, how can one conclude that when, after study by the TF, it was observed one of the major pieces of Intellectual Property (IP) that is often cited as an example of "patents gone wrong" was found to both allow for access to genetic testing and to do so in a cost efficient manner? Specifically, the report states:

> *"One surprising finding from the case studies was that the per-unit price of the full-sequence BRCA test, which often is cited as being priced very high, was actually quite comparable to the price of other full-sequence tests done by polymerase chain reaction (PCR), at nonprofit and for-profit testing laboratories."*

Thus, the public is not blocked from access to BRCA testing.

The Report also discusses the Cavanan's disease controversy. This unfortunate situation included a law suit and court action. However, the terms of the settlement have been sealed and consequently all that can be concluded is that redress mechanisms exist (both legal and social) that have resulted in public access to Canavan's disease testing in a manner that is acceptable to the interested public.

Therefore, the Report itself seems to have observed a lack of harm done by patents. At best, the Task Force findings support a conclusion that the patent system is self-correcting and do little if any harm.

The report contains inconsistent findings and flawed logic.

The Report mixes opinions and observations in a manner that makes it difficult to determine what are empirical facts and what are conclusions or comments. For example, in the section discussing academic research, one finds a mix of the two. Consider the following:

Line 433 et seq (emphasis in original):

> ***"Most academic scientists appear to be principally driven to carry out research not by the prospect of obtaining a patent but rather by a mix of motives,"***

This statement is followed by a series of what appear to be conclusions, including:

Line 439 et seq (emphasis in original):

> ***"The main factor driving the development of genetic tests in the academic setting is clinical need."***
>
> ***"Patents are not needed to give scientists an incentive to disclose gene-disease associations."***

The first statement appears to be the result of the anecdotal information. The second two statements seem to be conclusions intended to characterize the motivations of academics. These statements do not flow from the observation, or any empirical data included in the Report.

The Report continues on line 466 to state, again emphasized in the Report in bold type, that:

> ***"Although patented discoveries described in the case studies were also developed into tests, the fact that unpatented genetic discoveries were routinely developed into clinical genetic testing services suggests that patents are not needed for development of genetic tests. "***

It is unclear how one might draw any conclusion regarding the impact on patents from an observation that patented and unpatented discoveries were found to be developed. This simply does not follow. In fact, the structure of this sentence indicates bias.

An example that supports the proposition that IP acts as a positive force may be found in the Report on line 586 et seq, in **bold** type. The Report finds:

> ***"Exclusive licenses may be needed in some cases to provide a sufficient incentive to develop an***

invention…[and]"

"For the most part, patents covering genetic tests and related licensing practices do not appear to be causing wide or lasting barriers to patient access."

In this case, the Report discusses the licensing that comes from the movement of technology under IP regimes from one party to another. If, as the Report states, "licenses may be needed…" does that imply that the underlying use of IP was needed? Or that, in the absence of IP, technology would have been developed anyway? There is clear data in the report for the former, but none for the latter interpretation. What is meant by this?

It is also noted that the 77 public comments show no consensus regarding systemic problems with access to genetic testing caused by intellectual property. While some individuals and a few organizations state that genes should not be eligible for patenting, most organizations, including The Association of University Technology Managers (AUTM), the American Association of Clinical Chemistry (AACC), the American Association on of Medical Colleges (AAMC), the Biotechnology Industry Organization (BIO), state or imply that the Report scope is too broad and that there is no evidence of access problems meriting significant legislative or practice changes. Different commenters suggest distinct changes, but those that have been adopted in the Report represent unique or minority opinions.

In summary, The Body of the Report is unclear. It does not represent a consensus. It does not represent the views of many public commenters.

Report Recommendations

Comments on specific recommendations (Report recommendations are reproduced in bold/italic type (with footnotes omitted) to distinguish from my comments).

The Secretary of Health and Human Services should support and work with the Secretary of Commerce to promote the following statutory changes:

The creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes.

The creation of an exemption from patent infringement liability for those who use patent-protected genes

in the pursuit of research. Related health care and research entities also should be covered by this exemption.

Comment:

The Report states that the "first statutory change is narrowly tailored", but in contrast to the medical exemption passed by Congress under 35 USC 287, these suggested exemptions are focused on the technology rather than the user. If put into effect, they are little different than a change that makes so-called "gene patenting" virtually irrelevant and devoid of rights.

Further, a review of the compendium of public comments reveals of those who comment on a legislative option to address issues in gene patenting, the vast majority specifically state that they do not believe that such measures are warranted. Further, the Report itself supports this position even though the first two recommendations call for statutory change.

The Secretary should use her powers to discourage the seeking, the granting, and the invoking of simple association patent claims; it is the Committee's position that these claims represent basic laws of nature that cannot be invented around.

Comment:

This recommendation, if enacted by substantive regulation, would fundamentally change the scope of subject matter protection. This was one of the questions that the courts addressed in the Labcorp v. Metabolite cases. While the Supreme Court expressed interest in this issue, they eventually denied review. It is my belief that this suggestion is one that might be taken under advisement and considered further; however, action is premature.

The Secretary should develop mechanisms to promote voluntary adherence to the principles reflected in NIH's Best Practices for the Licensing of Genomic Inventions; the Organisation for Economic Co-Operation and Development's (OECD) Guidelines for Licensing of Genetic Inventions; the NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-wide Association Studies; and In the Public Interest: Nine Points to Consider in Licensing University Technology. The Secretary of Health and Human Services should also advocate that professional organizations involved in intellectual property

policy and practice in this area work together to build on those norms and practices as they relate to gene-based diagnostics by articulating more specific conditions under which exclusive licensing and nonexclusive licensing of uses relevant to genetic testing are appropriate. Professional societies should work cooperatively to forge consensus positions with respect to gene patenting and licensing policies.

The Secretary should encourage stakeholders (for example, industry, academic institutions, researchers, patients) to continue their work of developing a code of conduct that will enable broad access to such technologies.

Comment:

The best practices and points for consideration are already in de facto operation and have been extensively debated. To the extent that they remain voluntary, I agree that they are useful.

The Secretary should encourage holders of patents associated with genetic tests and their licensees to make information about patent licenses readily available either by making the signed licenses publicly available or by disseminating information about their technology and licensing conditions, including any terms that pertain to the type of license, field of use, and the scope of technologies that are still available.

As a means to enhance public access to information about the licensing of patents related to gene-based diagnostics, the Secretary should direct NIH to amend its Best Practices for the Licensing of Genomic Inventions to encourage licensors and licensees to include in their license contracts a provision that allows each party to disclose information about its licenses (including such factors as type of license, field of use, and scope) in order to encourage next-generation innovation.

Comment:

I agree that transparency serves to inform the public as to the IP landscape and helps in making economic and business decisions. I do not believe that the evidence supports the necessity for this suggestion. First, patent information is readily available from both the USPTO, the European Patent Office, the Japan Patent, private sources such as Google™ and others. However, license agreements often contain business confidential information. Second, there is no evidence of the need for public disclosure of the terms of license agreements to foster access to genetic testing or, indeed, for the development of any technology. It may be useful to suggest that the owner of any given patented technology be made public record, however,

to go beyond such disclosure risks discouraging private sector technology development and investment.

The Secretary should establish an advisory board, which would be available to provide ongoing advice about the public health impact of gene patenting and licensing practices. This advisory board would also be available to receive any reports of problems in patient access to genetic tests from the public and medical community. The board then could review new data collected on patient access and assess the extent to which access problems are occurring. One of the board's missions would also be to recommend what information should be systematically collected through iEdison so that iEdison can be used to research questions about licensing, including whether the licensing of genomic inventions has been conducted in accordance with NIH's Best Practices for the Licensing of Genomic Inventions. The advisory board also could provide input on the implementation of any future policy changes, including the other proposed recommendations in this report.

Comment:

I am neutral in regard to this suggestion since it is a suggestion regarding continuing oversight and has a clear pro and con for consideration by the full SACGHS Committee. Establishment of an advisory board would, however, carry administrative and personal costs that might be better used elsewhere. Since the Body of the Report provides ample evidence that IP systems appear to be self-correcting, it is unclear what, on balance, would be gained.

The Secretary should encourage Federal agencies within the Department of Health and Human Services to undertake the following actions:

Federal agencies should promote wider adoption of the principles reflected in NIH's Best Practices for the Licensing of Genomic Inventions and the OECD Guidelines for Licensing of Genetic Inventions, both of which encourage limited use of exclusive licensing for genetic/genomic inventions.

Federal agencies should encourage wider use of the Nine Points to Consider in Licensing University Technology. Points two and nine, including their explanatory text, are particularly relevant for genetic tests. For example, the explanatory text under point two recognizes that "licenses should not hinder clinical research, professional education and training, use by public health authorities, independent validation of test results or quality verification and/or control."

Comment:

These guidelines, best practices, and points to consider have been well vetted and shown to be both logical and reasonable. Therefore, to the extent that they remain suggestions, I concur that broad use of them aids in case-by-case consideration of issues in IP utilization and uptake.

Federal agencies should explore whether approaches to addressing patent thickets, including patent pools, clearinghouses, and cross-licensing agreements, could facilitate the development of multiplex tests or whole genome sequencing.

Comment:

First, I would note that there is little evidence of the presence of malignant “patent thickets.” However, in cases were multiple patent licenses are needed to develop a technology, it is agreed that mechanisms such as patent pools, clearinghouses, etc. have proven useful in the past. The private sector has delivered technologies, including MPEG compression, DVD technology, and home computers, that were purported to be stymied by patent thickets. I believe these mechanisms for facilitating technology access is reasonable. However, I am unclear as to the role of Federal Agencies per se in facilitating the development of these tools or where evidence would suggest that government intervention is indicated.

Federal agencies should provide more detailed guidance regarding the licensing of patents associated with genetic tests. In particular, this guidance should encourage the use of terms in licensing agreements, particularly those with exclusivity. Increasing the number of insurers that reimburse for the test or improving the specificity and sensitivity of the test are examples of milestones that a licensee could be required to meet to earn or maintain license rights.

Comment:

It is unclear why this is needed. The Body of the Report indicates the merit of the NIH Best Practices; the OECD’s licensing guidelines, and AUTM’s nine points for consideration. What additional guidance is needed, especially in light of the evidence in the Body of the Report that indicates, in most cases, IP is not acting to block technology access?

Because it is unclear whether the Bayh-Dole Act gives agencies authority to influence how grantees license patented inventions, the Secretary should seek clarification about this legal question. If it is determined that such authority exists, the Secretary should promulgate regulations that enable the Department's agencies to limit the ability of grantees to exclusively license inventions resulting from government funding when they are licensed for the genetic diagnostic field of use. Exceptions should also be allowed if a grantee can show that an exclusive license is more appropriate in a particular case, e.g., because of the high costs of developing the test. The Secretary should also direct NIH to make compliance with NIH's Best Practices for the Licensing of Genomic Inventions an important consideration in future grants awards.

Comment:

It is unclear whether additional regulation is required. Until that question is answered, this suggestion is premature.

The Secretary should recommend that the Secretary of Commerce advise USPTO to:
establish an advisory committee to provide advice about scientific and technological developments related to genetic tests and technologies that may inform its examination of patent applications in the realm of human genes. The Committee believes experts in the field could help USPTO in its development of guidelines on determinations of nonobviousness and subject matter eligibility in this field once pending court decisions such as Bilski v. Kappos are decided.

Comment:

It is agreed that continuing education, exploration of legal standards, and consideration of Court decisions is advisable. The issue of whether or not the USPTO requires the indicated advisory committee is unclear since it already has public advisory committees and has established an educational relationship with the NIH through its Office of the Director and Office of Technology Transfer. Further, the USPTO has demonstrated the ability to move with technology as evidenced by the development of examination guidelines for such things as computer implemented inventions, utility for biotechnology inventions, enforcement of the so-called "written description requirement" and implementation of case law including means-plus-function as elaborated in In re Donaldson. Therefore, it is unclear what evidence would support the establishment of yet another advisory group to oversee the USPTO.

Conclusion

Based in part on the above comments and other factors including participation in what appears to be a fundamentally flawed process, it is urged that the concept of ***first do no harm*** be followed. In this regard, at most, it seems that a factual report of study methodology is merited to be followed by the simple finding that, to the extent that “IP” and “Access to genetic testing” converge, there is no evidence of systemic harm.