-----Original Message-----
From: Jeffrey M. Libby [mailto:jlibby@MendelBio.COM]
Sent: Wednesday, May 03, 2006 3:40 PM
To: AB93Comments
Cc: neal Gutterson; thomas.e.kelley@monsanto.com; mWard@mofo.com; jlibby@mendelbio.com
Subject: Comments on Proposed Rules, Changes to Practice for Continuing Applications

Attn: Robert W. Bahr
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

From: Mendel Biotechnology, Inc.
Jeffrey M. Libby [mailto:jlibby@mendelbio.com]
Neal I. Gutterson [mailto:neal@mendelbio.com]

Re. Comments on Proposed Rules: "Changes to Practice for Continuing Applications, Requests
for Continued Examination Practice, and Applications Containing Patentably Indistinct
Claims" 71 Fed. Reg. 48 (January 3, 2006)
Dear Mr. Bahr:

Attached are the comments of Mendel Biotechnology, Inc. on the proposed rules changes to "Practice for Continuing Applications, RCE Practice, and Applications Containing Patentably Indistinct Claims." Our comments are attached as an MS Word file (our preferred format, complete with text formatting), and also embedded in the text of this message, below.

Please confirm receipt of this communication.
Sincerely,

Jeffrey M. Libby, Ph.D.
Senior Patent Agent
Mendel Biotechnology, Inc.

Neal I. Gutterson, Ph.D.
President and Chief Operating Officer
Mendel Biotechnology, Inc.

May 3, 2006

The Honorable Jon Dudas

Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Comments
P.O. Box 1450
Alexandria, VA 22313-1450

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Deputy Director
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Mendel is a pioneering plant genomics and biotechnology company, having been founded in 1997. From 1997 through 2003 Mendel employed a functional genomics strategy to identify the utilities of over 1000 key regulatory genes in plants. We have filed nearly 100 patent applications on the inventions identified through this work, and we are now collaborating with a range of partners in agriculture to create novel products that incorporate our technology. Our technologies include transgenic plants with, for example, improved water use efficiency, improved tolerances to a range of stresses (including drought, cold, heat, freezing, and several diseases), improved grain and biomass yield, and improved nitrogen use efficiency, as well as methods for creating such improved plants. We are developing products with corporate partners in row crops such as corn and soybean, in forestry crops such as poplar and eucalyptus, in ornamentals, and in bioenergy crops such as switchgrass and miscanthus. We continue to make inventions as we work to develop improved plant varieties that incorporate our technology.

Our primary source of intellectual property protection, the United States patent system, is designed to spur innovation and encourage research and

development of new products and services for the benefit of society. Particularly in the biotechnology sector, innovation protected by strong, predictable patents catalyzes investment and growth. The foundation of Mendel's value as a biotechnology company is our patent estate, both from issued patents and projected patents based on pending patents. Our ability to file continuation applications is critical to our current patent prosecution strategy, providing us the opportunity to obtain protection for the entirety of our inventions, as we will show in greater detail below.

Hence, it was with significant concern that we read the USPTO's proposal for rule changes in January of this year. The proposal would result in sweeping changes with the intention of alleviating the present patent application backlog. Clearly the new rules would have the effect of significantly curtailing the number of continuation applications that may be filed. However, it is not clear that the proposal is consistent with the high level of innovation in the biotechnology arts that has resulted in a leadership position for the United States in this industry. Nor is it apparent that the proposal will yield significant reductions in pendency and improvements in quality that the USPTO seeks.
We would like to address some of the present issues that may arise if the proposed rule changes are adopted, particularly with respect to how biotechnology is practiced today. The proposed rule changes to the practice of filing both divisional and continuation-in-part (CIP) are related and of concern, for reasons we will address in this document.

Biotechnology Companies File Early and Often

Because of intense competition for capital investments, biotechnology companies are pressured to file patent applications early and often to protect both the initial concepts of their discoveries and additional supported practical embodiments. Many of these companies begin as spin-offs from initial discoveries made within an academic setting. The early years of new biotechnology companies are unstable and uncertain. Attracting investors to these high-risk ventures is difficult. However, investors are continually drawn to such companies because of the potential for high returns realized upon the discovery, development and successful marketing and/or licensing of an effective treatment or valuable product. This competitive pressure drives smaller biotechnology companies to file patent applications on inventions early in the development stage so that they may obtain that first patent to generate investor interest and to meet milestone markers established by investors. Consequently, biotechnology companies file patent applications years before a product or technology has been fully developed or commercialized. During this time, they may agree to initial narrow patents and continue to perform "proof of concept" experiments to further support their initial discovery. This strategy is often adopted as a result of the USPTO's position that biotechnology is an "unpredictable art", requiring the later validation of applicant's invention scope to secure broad claims. Despite data provided by companies such as Mendel of the much increased predictability of certain types

of biotechnological inventions, the treatment of this field as "unpredictable" necessitates continuation practice to secure applicant's rightful scope. Further, with an initial patent in hand, patent owners can point to other pending applications (continuations) that may be broader and more comprehensive to secure further investor interest.

As an example, while a plant biotechnology company such as Mendel will have contemplated and claimed many crop products, the company will likely have had data largely in only one species of plant or other organism at the time of filing. In general, companies such as Mendel file patent applications based on promising data in an experimental plant system, such as *Arabidopsis thaliana*, tomato or rice. It is not uncommon for biotechnology arts patent applicants to have to submit additional empirical evidence during prosecution to support the applicability of the invention broadly in crop species. Sometimes this evidence can only come in the form of field data which can take years and significant financial resources to obtain. The time required to conduct such trials often requires applicants to file continuation applications. Further, obtaining substantive consideration of such experiments by patent examiners often requires the filing of continuations because of the USPTO's restrictive "after final practice". Absent the opportunity to file continuation applications, a biotechnology company may be forced to accept protection on less than it had a right to protect, i.e., the invention in its entirety. Frequently, in such a case, the only way a company will be able to protect the entire invention is by filing multiple stand-alone applications and by paying significantly more in filing and prosecution costs.

Biotechnology companies would be disproportionately impacted by these proposed rules, as they would be forced to choose between filing additional applications and funding R&D. Typically, resource-limited biotechnology companies will likely be forced to put their inventions into the public domain or secure reduced scope with associated reduced financial return. Without protection on commercially useful technologies, investors would not invest into the further development of such technologies. Consequently, promising technologies would simply languish on the laboratory shelves and gather dust.

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The use of continuation applications to obtain patent protection is a legitimate business practice for biotechnology companies. In the biotechnology patenting process, the commercial aspects of a particular invention may be modified over time based on the needs of potential financial partners. A small company working on a licensing agreement with a licensee may change the focus of the invention based on the needs of the licensee. For example, a company may decide to seek a product claim rather than a process claim or narrow the scope of its claims, all of which are supported in the original application. This ability to obtain financial support may well depend upon the existence of a continuation application, one in

which the claim form of interest to the investor or potential partner can be crafted.

The USPTO's Own Restriction Practice is Responsible for at Least Some of the Backlog

While there is truth in the assertion that "recognized value of patents" has led to the increased number of applications pending before the USPTO, at least some of the increase in application numbers would seem to be have been precipitated by changes in patent prosecution practice instituted by the USPTO itself. With respect to biotechnology applications, the USPTO formerly examined multiple nucleotide and/or peptide sequences within a single patent application. More recently, however, prosecution has been generally restricted to a single sequence invention per application. The reasons given by the USPTO for the focus on single sequence include the increasing content and complexity of sequence databases and related citations, which impact the ability of a patent examiner to conduct additional searches of the prior art. The result is that even closely related polypeptide sequences, having identical functions and yet differing by the most minor of changes, perhaps one or a few amino acid residues, are judged patentably distinct and thus restricted to separate patent applications. Efforts by the applicant to link sequences to a common invention are generally unsuccessful. Thus, to the biotechnology practitioner, it is not particularly surprising that the numbers of pending patent applications, particularly divisional applications, have increased significantly. Certainly, the biotechnology practitioner maintains many more patent applications than he or she would choose to maintain were restriction practice less illogical and onerous.

Under the proposed new rules, inventions comprising numerous sequence-based inventions would be filed either in a single application, and ultimately divided into numerous applications, or as numerous divisional patent applications filed in parallel. In the former instance, the ability to file continuation applications in response to shifting priorities would be severely limited or eliminated. The latter instance would impose a significant burden on the biotechnology art units at the USPTO due to the significant increase in application filings necessitated by the new rules. Because of the increased cost of filing and prosecuting numerous patents simultaneously, small companies would be at a significant disadvantage.

The USPTO's Own Practice Often Necessitates Responding with Minor Changes

In its justification for limiting continuation applications, the USPTO also stated in its background of the Proposed Rule Changes at the above cited website that "[i]n FY 2004, almost one-third of the 355,000 new patent applications had already been reviewed and rejected by the USPTO, but applicants resubmitted them mostly with only minor changes." However, it has been our experience that amendments after final rejections are often not entered based on the assertion that the proposed amendments would "raise new issues". Clearly, new material

entered into claims that require an exhaustive new search not be entered after a final rejection. However, "new issues" are raised even when proposed amendments are relatively trivial. We have even had "new issues" raised by amendments that were nothing more than simple narrowing of claims breadth. The result is an application being taken through only one proper round of examination on its merits. Clearly, this issue arises when the examiner perceives that he or she has limited time to perform two complete rounds of in-depth analysis, especially when complex issues are raised during prosecution. We generally respond to a new issues argument with a "resubmission" with "only minor changes" through a Request for Continued Examination (RCE). However, we and others may also choose to resubmit the application "with only minor changes" that clarify the contentious issues, such as by modifying claims or specification language, narrowing or broadening ranges, or adding some data to the specification that further supports the originally claimed invention. The new rules would curtail or eliminate this avenue to applicants, with only the promise that examiners will henceforth have the time and resources to perform a complete analysis on the merits. Even so, as the number of applications continue to increase in coming months or years, it is likely that the path to allowance will once again be limited or blocked by resource availability, without this escape route being provided.

Furthermore, examiners reviewing a heretofore unexamined patent application must review the specification as a whole and determine the patentability of the claims in light of that specification. In subsequent continuation applications, the examiner is more familiar with the disclosure and new claims are considered *de novo*, without the need to review the specification in the same detail. Thus, continuations are generally prosecuted in less time than newly considered applications. In our experience, however, we have found continuations are sometimes placed before an examiner who is different from the examiner scrutinizing the parent application, obviously a very inefficient use of USPTO resources.

Limiting divisional applications to involuntary applications and claims in CIPs to benefit of filing date of the CIP places an onerous burden on the biotechnology practitioner

The proposed new rules limit divisional applications only to those directed to inventions subject to unity of invention (PCT Rule 13) or restriction requirements (35 USC 121). The divisional application would thus contain only claims to inventions identified in the unity or restriction requirement and not elected in the prior-filed application, and may claim the benefit of only a single prior-filed nonprovisional application.

Unfortunately, the proposed rule changes do not account for changes in scientific or business priorities. In the areas of bioinformatics, gene discovery, expression analysis, transcript profiling and proteomics, sequence discoveries often do not

come one at a time, but in groups, and sometimes large groups. Related sequences (for example, orthologs from unrelated species of plant or animal, or various sequences with minor mutations) may behave similarly *in vivo* or in diagnostic tests. Many of these can be predicted to work early in the discovery process. A single application may list numerous related and newly identified sequence inventions that round out the scope of an invention and can yield an advance in medicine, diagnostics, or improved crops or animals. However, while each sequence invention constitutes a potentially valuable novel invention, each is not necessarily awarded an initially high priority and made the subject of claims. Only after being subjected to lengthy testing and analysis, including clinical or field trials, can the optimum sequence invention be best appreciated for its value. Economic considerations and governmental regulations may require years to sort out the most commercially advantageous inventions, and one or more generations of continuation applications to claim the optimum and most useful invention are often required.

By way of an example with which we have first hand and real experience, a patent application contains more than one polypeptide sequence that confer valuable traits to commercial plants. In initial screens with a relatively few lines of model plants, some sequences perform better than others that are closely related, and the former become the subject of the claims. The lower priority sequences, which are indeed disclosed and are indeed inventions, are also claimed but become the subject of a restriction requirement and are withdrawn from consideration in that application. Some time later, after reviewing more rigorous trials, our appreciation of the commercial value of the initially lower priority sequences may increase significantly based on field performance criteria. Under the current system, which beautifully protects the American innovator, the applicant may file a continuation application in the same line of applications, claiming priority from the first application, years after the initial filing. Under the newly proposed rules, however, this avenue to commercial success would likely be lost. Instead of rewarding the American inventor with the prospect of maximizing commercial success with an innovative patent system, the best inventions may be lost with a mediocre patent system that adds complexity and places additional and unnecessary constraints on the inventor.

The PTO's Proposed Rules are Retroactive

Many biotechnology companies have adopted the practice of filing continuation applications as a matter of business practice and good sense, properly operating their patent practice within the limits allowed by law and existing rules. To change that practice now, without some means to "grandfather" the content of pending applications under the old rules, could result in many companies losing the ability to prosecute further much of their intellectual property portfolios.

The retroactivity of the proposed rules is particularly disturbing and appears to deny due process under the Administrative Procedures Act. That is, if a

continuing application is already pending, second and subsequent continuation applications would be prohibited without the granting of a petition. The proposed claim limits would also be applied to any unexamined application pending at the USPTO at the time the Rules changes are adopted. This retroactive change could severely disadvantage companies that established patent prosecution strategies based on current continuation rules many years ago, but now will be forced to shift strategy in mid-prosecution for a large number of pending cases. In these cases, we would be prohibited from filing any continuing applications without the granting of a petition and without notice.

The Proposed Changes to the Rules Will Increase Costs and Uncertainty

The proposed rule changes are particularly burdensome for small companies. As noted above, our emerging patent estate is our most valuable asset and the gold standard by which venture capitalists and strategic partners evaluate investment candidates and business opportunities. The proposed changes to the continuation rules will likely result in substantial and immediate increased costs to obtain patent protection. Large corporate entities, having identified numerous potentially valuable inventions, are better able to file numerous applications simultaneously (that is, in parallel) and thus retain the ability to prosecute numerous inventions at a future date. Because of the high cost of filing and simultaneously prosecuting applications, small companies have traditionally filed applications one after another (that is, serially), relying on the disclosure and filing date of the first application in the series. The proposed rule changes thus favor larger companies over smaller, newer start-up companies.

In addition, the cost of obtaining patent protection will dramatically increase as a result of the proposals to limit the number of claims that will be initially examined. We will be required to review claim designation and prosecution strategies in light of the new changes. The USPTO will then have to process all of these designations before examination starts. These burdens are further compounded by the USPTO's proposal to make these rules retroactive.

Further, the USPTO proposals will increase uncertainty for our developing patent estate, as these rule changes are likely to be challenged in the courts. During the period of uncertainty, while the legal system decides the fate of these rules, we will be required to follow the rules (or forgo obtaining patents), frequently resulting in patents of lesser value, which could have a significant negative effect on our business.

Not everyone will be against the proposed rule changes; those who make use of biotechnology inventions without expending large sums of money and years of effort (currently known as "infringers") may have considerable reason to find comfort with the new rules. Given the difficulties in obtaining ample breadth around sequence-based inventions, companies (particularly small companies) that can only prosecute and maintain limited numbers of narrowly-focused

sequence-based applications, filed in parallel, will lose the ability to limit the use of related sequences and inventions, particularly after a second generation of continuation applications have been filed. Others would then be free to make use of related inventions not covered by the scope of the inventor's pending claims, including inventions that later prove to be commercially valuable and that could otherwise be protected with a serial filing strategy.

The proposed rules to limit continuations will not achieve the objective

Unfortunately, the proposed rule changes will adversely impact our ability to innovate by limiting the number of sequence inventions that can be patented, increasing patent prosecution costs, and making it more difficult for us to attract financing for products that require generally 7-10 years to reach the marketplace. The USPTO also indicates the proposed rules are intended to address the issue of delayed public notice of intellectual property rights. Instead of addressing these concerns however, Mendel believes these rules if adopted will increase both the backlog and pendency and create unintended consequences for the commercial prospects of small technology-focused companies such as Mendel.

The present system seems to satisfy neither the overtaxed patent examiner or the practitioner who must submit, and then resubmit, more applications than they feel are necessary or optimum. The solution that the USPTO has proposed would effectively curtail the number of continuations that practitioner may file. The worthy goal of this limitation would seem to be more in-depth, careful and complete analysis of a pending application by the now unburdened examiner, thus reducing or, ideally, eliminating the need for the continuation. This analysis, if correct, does not take into account the fact that the number of applications are yet increasing, that the examiner will be overburdened again in the future, and the same problems will arise with less or no recourse for the practitioner.

Alternative Solutions Do Exist That Would Better Serve American Inventors

The solutions proposed by the USPTO in its new rules ***may*** have the temporary effect of alleviating the burden on patent examiners. However, as the number of applications pending before the USPTO continues to increase out of proportion to the number of examiners and the time available to them, the limitation problems that currently affect the USPTO and impact the examination of patent application will once again predominate. In the interim, however, the patent practitioner will face increasingly burdensome and expensive prosecution requirements, and will likely and henceforth lose the ability to continue prosecuting inventions that, because of changing priorities, evolve into successful products and become appreciated for their commercial value.

Since the problem that emerges is one of resource limitation, two possible solutions can be envisioned. The first, proposed by the USPTO, attacks the problem by limiting input. The second would attack the problem by increasing

output. The former solution limits inventiveness, particularly American inventiveness, whereas the latter would have the ultimate effect of increasing the number of patent applications and inventions that may be successfully prosecuted and ultimately allowed. As indicated above in our arguments, there is significant value to be added by the latter approach. For the latter to succeed, however, creative thinking must be applied in order to add resources or make the best use of available resources.

While it is not our intention here to propose what we believe are the optimum solutions to a complex and ever-compounding problem, we believe increased specialization to make use of available resources more cost effectively can accomplish much. Similar to various foreign patent offices, searching the prior art can be performed by specialists to a greater degree than is done at present, and particularly with the increased use of outsourcing (with the obvious and strong preference of U.S.-based outsourcing). This may be particularly efficacious for biotechnology-based applications, for which the search for related sequences can be performed very effectively outside the USPTO. Again using a foreign model (in this case with respect to unity of invention practice), the prosecution of multiple, closely-related inventions in single applications, that is, without the need for restriction, would also address to some degree the overabundance of new applications. Since the inventions being searched would be limited to those closely related (but currently considered distinct, this would provide a volume/cost benefit savings. A *reasonable* fee charged for multiple inventions may be a practical consideration. In any event, the illogical and onerous restriction practice imposed by the USPTO on the biotechnology practitioner must be reexamined and reconsidered.

The key issue at hand is that creative thinking is a better approach than stifling innovation. Any new rule that limits the ability of the inventor to protect his or her intellectual property under the guise of increasing patent application throughput is not going to do that inventor any favors.

Conclusion

Mendel Biotechnology, Inc. has a profound appreciation for the dedication, performance and hard work performed by the USPTO, and recognizes the need to improve the patent prosecution process. However, for our reasons stated above, we believe that the proposed rule changes to speed up patent prosecution and alleviate the current application backlog would simultaneously place an undue burden on the patent practitioner, and more specifically, the practitioner in the biotechnology arts.

Considering the sizable and adverse impact these proposed changes are likely to have on patent prosecution practice, we ask that the USPTO reconsider the proposed rule changes. We recognize the significant resource limitations at the USPTO and its mounting needs. It is hoped that the USPTO similarly recognizes the limited resources of patent practitioners, particularly those engaged at small biotechnology companies.

Americans are innovators. With the Constitution and the Patent Act of 1790, the very concept of patent practice as a government institution became a U.S. innovation. However, increasing the complexity of and further constraining patent prosecution does not seem particularly innovative. We believe that the most appropriate next step, rather than the new rules proposed by the USPTO, is a comprehensive examination dealing with alleviating the resource limitations of the USPTO using creative, productive and positive approaches to the problem.

Sincerely,

Mendel Biotechnology, Inc.

Jeffrey M. Libby, Ph.D.
Senior Patent Agent
Mendel Biotechnology, Inc.

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Comments on the

United States Patent & Trademark Office

Proposed Rules Changes Concerning

Continuation Practice and Claim Limitations

May 3, 2006

VIA ELECTRONIC MAIL

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The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
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Under the proposed new rules, inventions comprising numerous sequence-based inventions would be filed either in a single application, and ultimately divided into numerous applications, or as numerous divisional patent applications filed in parallel. In the former instance, the ability to file continuation applications in response to shifting priorities would be severely limited or eliminated. The latter instance would impose a significant burden on the biotechnology art units at the USPTO due to the significant increase in application filings necessitated by the new rules. Because of the increased cost of filing and prosecuting numerous patents simultaneously, small companies would be at a significant disadvantage.

The USPTO's Own Practice Often Necessitates Responding with Minor Changes

In its justification for limiting continuation applications, the USPTO also stated in its background of the Proposed Rule Changes at the above cited website that "[i]n FY 2004, almost one-third of the 355,000 new patent applications had already been reviewed and rejected by the USPTO, but applicants resubmitted them mostly with only minor changes." However, it has been our experience that amendments after final rejections are often not entered based on the assertion that the proposed amendments would "raise new issues". Clearly, new material entered into claims that require an exhaustive new search not be entered after a final rejection. However, "new issues" are raised even when proposed amendments are relatively trivial. We have even had "new issues" raised by amendments that were nothing more than simple narrowing of claims breadth. The result is an application being taken through only one proper round of examination on its merits. Clearly, this issue arises when the examiner perceives that he or she has limited time to perform two complete rounds of in-depth analysis, especially when complex issues are raised during prosecution. We generally respond to a new issues argument with a "resubmission" with "only minor changes" through a Request for Continued Examination (RCE). However, we and others may also choose to resubmit the application "with only minor changes" that clarify the contentious issues, such as by modifying claims or specification language, narrowing or broadening ranges, or adding some data to the specification that further supports the originally claimed invention. The new rules would curtail or eliminate this avenue to applicants, with only the promise that examiners will henceforth have the time and resources to perform a complete analysis on the merits. Even so, as the number of applications continue to increase in coming months or years, it is likely that the path to allowance

will once again be limited or blocked by resource availability, without this escape route being provided.

Furthermore, examiners reviewing a heretofore unexamined patent application must review the specification as a whole and determine the patentability of the claims in light of that specification. In subsequent continuation applications, the examiner is more familiar with the disclosure and new claims are considered *de novo*, without the need to review the specification in the same detail. Thus, continuations are generally prosecuted in less time than newly considered applications. In our experience, however, we have found continuations are sometimes placed before an examiner who is different from the examiner scrutinizing the parent application, obviously a very inefficient use of USPTO resources.

Limiting divisional applications to involuntary applications and claims in CIPs to benefit of filing date of the CIP places an onerous burden on the biotechnology practitioner

The proposed new rules limit divisional applications only to those directed to inventions subject to unity of invention (PCT Rule 13) or restriction requirements (35 USC 121). The divisional application would thus contain only claims to inventions identified in the unity or restriction requirement and not elected in the prior-filed application, and may claim the benefit of only a single prior-filed nonprovisional application.

Unfortunately, the proposed rule changes do not account for changes in scientific or business priorities. In the areas of bioinformatics, gene discovery, expression analysis, transcript profiling and proteomics, sequence discoveries often do not come one at a time, but in groups, and sometimes large groups. Related sequences (for example, orthologs from unrelated species of plant or animal, or various sequences with minor mutations) may behave similarly *in vivo* or in diagnostic tests. Many of these can be predicted to work early in the discovery process. A single application may list numerous related and newly identified sequence inventions that round out the scope of an invention and can yield an advance in medicine, diagnostics, or improved crops or animals. However, while each sequence invention constitutes a potentially valuable novel invention, each is not necessarily awarded an initially high priority and made the subject of claims. Only after being subjected to lengthy testing and analysis, including clinical or field trials, can the optimum sequence invention be best appreciated for its value. Economic considerations and governmental regulations may require years to sort out the most commercially advantageous inventions, and one or more generations of continuation applications to claim the optimum and most useful invention are often required.

By way of an example with which we have first hand and real experience, a patent application contains more than one polypeptide sequence that confer valuable traits to commercial plants. In initial screens with a relatively few lines of model plants, some sequences perform better than others that are closely related, and the former become the subject of the claims. The lower priority sequences, which are indeed disclosed and are indeed inventions, are also claimed but become the subject of a restriction requirement and are withdrawn from consideration in that application. Some time later, after reviewing more rigorous trials, our appreciation of the commercial value of the initially lower priority sequences may increase significantly based on field

performance criteria. Under the current system, which beautifully protects the American innovator, the applicant may file a continuation application in the same line of applications, claiming priority from the first application, years after the initial filing. Under the newly proposed rules, however, this avenue to commercial success would likely be lost. Instead of rewarding the American inventor with the prospect of maximizing commercial success with an innovative patent system, the best inventions may be lost with a mediocre patent system that adds complexity and places additional and unnecessary constraints on the inventor.

The PTO's Proposed Rules are Retroactive

Many biotechnology companies have adopted the practice of filing continuation applications as a matter of business practice and good sense, properly operating their patent practice within the limits allowed by law and existing rules. To change that practice now, without some means to "grandfather" the content of pending applications under the old rules, could result in many companies losing the ability to prosecute further much of their intellectual property portfolios.

The retroactivity of the proposed rules is particularly disturbing and appears to deny due process under the Administrative Procedures Act. That is, if a continuing application is already pending, second and subsequent continuation applications would be prohibited without the granting of a petition. The proposed claim limits would also be applied to any unexamined application pending at the USPTO at the time the Rules changes are adopted. This retroactive change could severely disadvantage companies that established patent prosecution strategies based on current continuation rules many years ago, but now will be forced to shift strategy in mid-prosecution for a large number of pending cases. In these cases, we would be prohibited from filing any continuing applications without the granting of a petition and without notice.

The Proposed Changes to the Rules Will Increase Costs and Uncertainty

The proposed rule changes are particularly burdensome for small companies. As noted above, our emerging patent estate is our most valuable asset and the gold standard by which venture capitalists and strategic partners evaluate investment candidates and business opportunities. The proposed changes to the continuation rules will likely result in substantial and immediate increased costs to obtain patent protection. Large corporate entities, having identified numerous potentially valuable inventions, are better able to file numerous applications simultaneously (that is, in parallel) and thus retain the ability to prosecute numerous inventions at a future date. Because of the high cost of filing and simultaneously prosecuting applications, small companies have traditionally filed applications one after another (that is, serially), relying on the disclosure and filing date of the first application in the series. The proposed rule changes thus favor larger companies over smaller, newer start-up companies.

In addition, the cost of obtaining patent protection will dramatically increase as a result of the proposals to limit the number of claims that will be initially examined. We will be required to review claim designation and prosecution strategies in light of the new changes. The USPTO will then have to process all of these designations before examination starts. These burdens are further compounded by the USPTO's proposal to make these rules retroactive.

Further, the USPTO proposals will increase uncertainty for our developing patent estate, as these rule changes are likely to be challenged in the courts. During the period of uncertainty, while the legal system decides the fate of these rules, we will be required to follow the rules (or forgo obtaining patents), frequently resulting in patents of lesser value, which could have a significant negative effect on our business.

Not everyone will be against the proposed rule changes; those who make use of biotechnology inventions without expending large sums of money and years of effort (currently known as "infringers") may have considerable reason to find comfort with the new rules. Given the difficulties in obtaining ample breadth around sequence-based inventions, companies (particularly small companies) that can only prosecute and maintain limited numbers of narrowly-focused sequence-based applications, filed in parallel, will lose the ability to limit the use of related sequences and inventions, particularly after a second generation of continuation applications have been filed. Others would then be free to make use of related inventions not covered by the scope of the inventor's pending claims, including inventions that later prove to be commercially valuable and that could otherwise be protected with a serial filing strategy.

The proposed rules to limit continuations will not achieve the objective

Unfortunately, the proposed rule changes will adversely impact our ability to innovate by limiting the number of sequence inventions that can be patented, increasing patent prosecution costs, and making it more difficult for us to attract financing for products that require generally 7-10 years to reach the marketplace. The USPTO also indicates the proposed rules are intended to address the issue of delayed public notice of intellectual property rights. [1] Instead of addressing these concerns however, Mendel believes these rules if adopted will increase both the backlog and pendency and create unintended consequences for the commercial prospects of small technology-focused companies such as Mendel.

The present system seems to satisfy neither the overtaxed patent examiner or the practitioner who must submit, and then resubmit, more applications than they feel are necessary or optimum. The solution that the USPTO has proposed would effectively curtail the number of continuations that practitioner may file. The worthy goal of this limitation would seem to be more in-depth, careful and complete analysis of a pending application by the now unburdened examiner, thus reducing or, ideally, eliminating the need for the continuation. This analysis, if correct, does not take into account the fact that the number of applications are yet increasing, that the examiner will be overburdened again in the future, and the same problems will arise with less or no recourse for the practitioner.

Alternative Solutions Do Exist That Would Better Serve American Inventors

The solutions proposed by the USPTO in its new rules ***may*** have the temporary effect of alleviating the burden on patent examiners. However, as the number of applications pending before

[1]See for example, Fed. Reg., vol. 71, no. 1, at page 48 (right column) and page 49 (center column).

the USPTO continues to increase out of proportion to the number of examiners and the time available to them, the limitation problems that currently affect the USPTO and impact the examination of patent application will once again predominate. In the interim, however, the patent practitioner will face increasingly burdensome and expensive prosecution requirements, and will likely and henceforth lose the ability to continue prosecuting inventions that, because of changing priorities, evolve into successful products and become appreciated for their commercial value.

Since the problem that emerges is one of resource limitation, two possible solutions can be envisioned. The first, proposed by the USPTO, attacks the problem by limiting input. The second would attack the problem by increasing output. The former solution limits inventiveness, particularly American inventiveness, whereas the latter would have the ultimate effect of increasing the number of patent applications and inventions that may be successfully prosecuted and ultimately allowed. As indicated above in our arguments, there is significant value to be added by the latter approach. For the latter to succeed, however, creative thinking must be applied in order to add resources or make the best use of available resources.

While it is not our intention here to propose what we believe are the optimum solutions to a complex and ever-compounding problem, we believe increased specialization to make use of available resources more cost effectively can accomplish much. Similar to various foreign patent offices, searching the prior art can be performed by specialists to a greater degree than is done at present, and particularly with the increased use of outsourcing (with the obvious and strong preference of U.S.-based outsourcing). This may be particularly efficacious for biotechnology-based applications, for which the search for related sequences can be performed very effectively outside the USPTO. Again using a foreign model (in this case with respect to unity of invention practice), the prosecution of multiple, closely-related inventions in single applications, that is, without the need for restriction, would also address to some degree the overabundance of new applications. Since the inventions being searched would be limited to those closely related (but currently considered distinct, this would provide a volume/cost benefit savings. A *reasonable* fee charged for multiple inventions may be a practical consideration. In any event, the illogical and onerous restriction practice imposed by the USPTO on the biotechnology practitioner must be reexamined and reconsidered.

The key issue at hand is that creative thinking is a better approach than stifling innovation. Any new rule that limits the ability of the inventor to protect his or her intellectual property under the guise of increasing patent application throughput is not going to do that inventor any favors.

Conclusion

Mendel Biotechnology, Inc. has a profound appreciation for the dedication, performance and hard work performed by the USPTO, and recognizes the need to improve the patent prosecution process. However, for our reasons stated above, we believe that the proposed rule changes to speed up patent prosecution and alleviate the current application backlog would simultaneously place an undue burden on the patent practitioner, and more specifically, the practitioner in the biotechnology arts.

Considering the sizable and adverse impact these proposed changes are likely to have on patent prosecution practice, we ask that the USPTO reconsider the proposed rule changes. We recognize the significant resource limitations at the USPTO and its mounting needs. It is hoped that the USPTO similarly recognizes the limited resources of patent practitioners, particularly those engaged at small biotechnology companies.

Americans are innovators. With the Constitution and the Patent Act of 1790, the very concept of patent practice as a government institution became a U.S. innovation. However, increasing the complexity of and further constraining patent prosecution does not seem particularly innovative. We believe that the most appropriate next step, rather than the new rules proposed by the USPTO, is a comprehensive examination dealing with alleviating the resource limitations of the USPTO using creative, productive and positive approaches to the problem.

Sincerely,

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