



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

1225 Eye St., N.W., Suite 400
Washington, DC 20005

July 21, 2003

Mail Stop Comments–Patents
Commissioner for Patents
Attn.: Robert A. Clarke
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Mr. Clarke:

I am pleased to offer the views of the Biotechnology Industry Organization (BIO) in response to the *Request for Comments on the Study of the Changes Needed to Implement a Unity of Invention Standard in the United States*, 68 Fed. Reg. 27536 (May 20, 2003).

BIO is a trade association representing more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products. Our membership represents a complete cross section of the industry, from small start-ups to large pharmaceutical and agricultural biotechnology companies.

General Comments

Patents are critical assets for all of BIO's member companies. Strong and predictable patent protection makes possible the flow of risk capital that is vital to achieving biotechnology's promise. BIO supports the PTO's efforts to strengthen and improve the patent system; we also support the goals of the 21st-Century Strategic Plan and in particular, we commend the PTO for undertaking a study to evaluate changes needed to implement a unity of invention standard in the United States. In our statement before the House Judiciary Subcommittee on Courts, the Internet and Intellectual Property oversight hearing on the United States Patent and Trademark Office in April of this year, we urged Congress to eliminate its practice of diverting the PTO funds to non-

PTO programs and asked Congress to implement restriction reform in conjunction with enactment of the current PTO fee bill, H.R. 1561 pending before Congress.¹

Restriction practice, whether conducted under the “independent and distinct” standard of current 35 U.S.C. § 121 or the “unity of invention” standard of the Patent Cooperation Treaty (PCT), is essentially a procedural tool with which the PTO regulates the use of its resources. Unfortunately, the way restriction is currently carried out critically affects the biotechnology industry. Few other industries are so dependent on the ability to secure patent protection for their inventions.

Reforming restriction practice in the PTO is a matter of extreme urgency for our industry. The PTO’s current restriction practices in biotechnology applications are fundamentally inefficient and, in our view, simply unreasonable. Particularly in the last three to five years, restrictions have been imposed with ever-increasing granularity. Examiners assert, with no evidentiary or legal support, that *any* structural or functional difference between related embodiments of an invention is enough to justify restriction. Applicants frequently receive requirements enumerating dozens or *hundreds* of “independent and distinct” inventions, even when all the original claims relate to the same basic discovery. Surely such practices do not fairly “balance the interest of granting an applicant reasonable breadth of protection in a single patent against the burden on the PTO of examining multiple inventions in a single application,” as outlined in the present Request for Comments.

The biotechnology industry suffers disproportionately from these practices. Because the technology is so complex, a biotechnology applicant must claim several related products and methods to obtain complete and commercially relevant coverage for an invention. Under the “independent and distinct” standard as it is now applied, the applicant must file a series of divisional applications to patent, in essence, different facets of the same inventive concept. The financial burden of filing, prosecuting and maintaining a multiplicity of patents is significant.² Moreover, the proliferation of applications creates chaos in the PTO and the marketplace as claims are issued in several patents over a period of years, rather than in a single patent.

Most companies in our industry operate in extremely constrained financial circumstances. Restriction requirements imposed loosely and without management oversight create immense and unnecessary additional costs that can cripple biotech companies. Indeed, the majority of BIO’s members are small businesses that must decide whether to allocate resources to legal services or to basic research and product development. It is fundamentally unfair to force these companies to choose between

¹ Statement of the Biotechnology Industry Organization before the United States House of Representatives Committee on the Judiciary, Subcommittee on Courts, the Internet and Intellectual Property, April 3, 2003; <http://www.bio.org/ip/pto/20030403.pdf>

² Some applicants are forced to spend more than \$500,000, including PTO fees and attorney costs, to fully protect a single invention.

unnecessary legal costs and R&D investments that might help bring a promising therapy to the market.

BIO believes that the business interests of our industry, the PTO's administrative interests and the public interest will all be served by making the most efficient use of the available resources. In our view, the PTO's resources will be best utilized if all substantially similar inventions disclosed in an application are examined concurrently. In this regard, we believe that inventions should be considered substantially similar for examination purposes, and thus examined together, when a single thorough and properly executed search will identify the prior art relevant to all the inventions.³

While specific remarks will be offered below, BIO members believe it is important to fundamentally alter how the PTO manages the work that is done in an application, regardless of the standard that is devised to replace the current standard reflected in 35 U.S.C. 121. Currently, the PTO can unilaterally dictate how many applications must be filed to obtain effective patent coverage. Moreover, the costs of multiple filings, particularly in our field, bear no relation to the amount of additional work that the PTO must perform. Thus, to obtain effective patent coverage, a typical biotech applicant must pay three to six times the fees that reasonably should be collected to conduct examination of the invention. This is unfair and, ultimately, unsustainable.

Certainly our industry appreciates that there are often added complexities encountered in examination of biotechnology inventions. We accordingly support adopting measures to allow the PTO to recover the fees that correspond to the actual work needed to ensure a thorough and complete examination of each application.

BIO members believe a new standard can be devised that will reflect the realities of the modern examination environment. Such a standard should recognize that the PTO has to perform two distinct classes of work. First, the office must conduct thorough and accurate searches of prior art. Second, the PTO must apply patentability standards correctly to the presented claims. The two main types of labor provide a natural foundation for a system to assess additional fees where the PTO must perform additional work (on average). Specifically, the PTO could devise and operate under a standard that sets fees based on (1) whether additional assessment of patentability issues arises and (2) whether additional searches are required.

³ We particularly note that a thorough search for several inventions (e.g., a novel group of closely related genetic sequences, the corresponding polypeptide expression products and the corresponding antibodies) may well be broader in scope than a search sufficient for one product. However, a consolidated search and examination will make better use of resources than several successive—and largely overlapping—searches and examinations. With reference to this example, a proper search for *each* of the genetic sequence, expression product and antibody inventions begins with a computer-based search of the *same* set of biosequence databases. There is no rational basis for requiring the PTO to perform this search more than once. *See also* Administrative Instructions to the PCT, Annex B, Example 17 (unity of invention accepted between claims to “protein X” and “DNA sequence encoding protein X”).

BIO members realize that a thorough examination of several closely linked inventions will consume more resources when non-prior art issues play a significant role in determining patentability. In particular, issues under 35 U.S.C. §§ 101 and 112 often arise in the course of examining inventions where no issues relating to novelty or obviousness remain. For example, examining a method of using a patentable (or patented) biotechnology product in a novel therapeutic method may require consideration of issues that did not need to be taken up to find the product patentable. Throughout our comments, we refer to inventions that are closely linked in this manner as “related.” We note that these “related” inventions typically do not call for a substantially different search, but often raise significant divergent patentability issues not based on prior art.

Our members also recognize that a single application may disclose different inventions that would require substantially divergent searches and would raise unique non-prior art patentability issues. No gain in efficiency would come from searching or examining such inventions, which we refer to as “unrelated” inventions, in the same application. We thus would support allowing the PTO to either require restriction between unrelated inventions or charge a full additional set of fees. Determinations of the “relatedness” of various aspects or embodiments of an invention should be made without regard to the manner in which the invention is claimed.

The approach that we advocate would justify additional fees based on how the related claims are presented, rather than on a pure “unity of invention” standard applied only with reference to the prior art. Specifically, “unity of invention” under the standard of the PCT evaluates whether a shared technical feature distinguishes the inventions over the prior art. We would advocate for a unity of invention–type model for reforming restriction practice in the United States.

Responses to Specific Questions

Issue 1 Should the PTO study EPC-style limitations on claiming as part of a unity implementation?

BIO believes that European-style claim structure does have benefits. For example, adoption of a multiple–multiple dependent claim structure would make examination more efficient and harmonize U.S. claim structure with those used in patent offices around the world. However, an EPO-style rule allowing only one independent claim per statutory category of invention would impose artificial restrictions on the scope or manner of claiming related inventions that could be examined in a single application. In biotechnology, it is often the case that several different products are essentially unitary or related inventions. For example, in the case of a novel gene, claims to DNA corresponding to the gene, the protein it encodes and an antibody specific for the protein define different aspects of the same inventive concept. It is entirely appropriate to claim such products in independent claims. Similarly, artificial restrictions would result from a “one independent claim” rule in the case of intermediate and final chemical products.⁴

⁴ See Administrative Instructions to the PCT, Annex B, part 1(g).

Should the presumption of validity under 35 U.S.C. § 282 differ for independent and dependent claims?

No. In biotechnology, as in every other industry, patent holders depend on the ability to effectively enforce their claims. The presumption of validity under 35 U.S.C. § 282 creates the proper environment for enforcing claims that have been the subject of a thorough PTO examination.

Under well-established U.S. law, every claim in a patent defines a distinct invention, and each such claim is presumed to be valid. A thorough and detailed examination of every claim is essential to maintaining that presumption. The real-world value of having independently valid and enforceable claims is apparent in litigation. A narrower claim, often in the form of a dependent claim, may survive an attack based on prior art or other patentability standards where a broader independent claim may not. In addition, procedural complications would arise from a standard that afforded a presumption of validity only for certain claims and not others. A dual-standard “presumption” would be unworkable.

It is generally the experience of BIO members that EPO examiners are in fact attentive to dependent claims. Our collective experience suggests that the claims of European patents are as enforceable as are those in U.S. patents. A thorough examination of every presented claim is thus not inherently incompatible with administering a unity-of-invention standard.

We observe that the more liberal European practice in respect of multiple dependent claims makes complex claim sets much more manageable than equivalent claims drafted according to U.S. practice. We believe that such practice facilitates efficient examination in the EPO. We therefore urge the PTO to consider amending U.S. practice in this regard.

Issue 2 Should the United States allow examination of additional inventions on payment of fees?

Yes. The success of the PTO’s 21st-Century Strategic Plan hinges on making the most efficient use of examination resources. Policies that result in examination of all related inventions (i.e., those involving substantially similar searches) at the same time will strengthen and support the viability of the plan.

BIO realizes that examining related inventions together with a “main” invention in an application will require additional increments of examiners’ time and effort. BIO members support a standard that would allow the Patent Office to collect additional fees that fairly reflect the resources expended by the office to examine applications.

We believe the PTO should support a fee structure that uses two tiers of additional fees in applications presenting claims that will generate resource requirements beyond those needed to examine a “single” invention. Below is an exemplary, but not exhaustive, list of a “single” biotechnology invention:

A typical biotechnology application will concern inventions based on discovery and characterization of a particular gene. Claims often are presented to nucleic acids that encode the gene, the polypeptide that the gene encodes, and antibodies that bind “generically” to the polypeptide. Methods of expressing the gene (i.e., making the polypeptide), of making antibodies using conventional hybridoma techniques, or to conventional cell lines that express that gene are also typically presented. Additionally, a biotechnology patent applicant may present claims that use a homology definition relative to a specific reference sequence.

In some instances, claims may be presented to an invention that includes a number of distinct genes as elements. For example, a set of claims might be presented to a “chip” comprising a number of different proteins or nucleic acids affixed thereto. Such an invention, recited as a combination of different proteins or nucleic acids, should be considered a single invention if it requires the presence of all the different proteins or nucleic acids. Similarly, a set of nucleic acid or protein species might be considered as a single invention if the utility of the invention depends on the presence of all the recited nucleic acids or proteins. For example, a set of genes might be expressed by a cancer cell in a certain pattern that is detected by a set of nucleic acid sequences affixed to a substrate or by an appropriate set of primers for use in a polymerase chain reaction. The set of nucleic acids might act in concert to effect a particular physiologic function, produce a desired phenotype in an organism, or catalyze a series of biochemical reactions to convert a substrate into a desired product.

Furthermore, in the case of chemical inventions, and in particular, with claims to classes of related molecules, the Markush format allows an applicant to recite several alternative limitations within a single claim. As such, these limitations are equivalent to several different claims, each reciting one of the alternatives. Such claims may represent a single inventive concept or related inventions, depending upon the nature of the shared subject matter. Seldom will such claims cover unrelated inventions. Particularly in the chemical field, the use of multiple “nested” Markush groups (i.e., claim elements in which each of several alternatives may be selected from several second-level alternatives) has led to the presentation of claims that embrace a vast number of compounds. The fact that such claims may embrace a vast number of compounds does not affect the analysis required under the relevant statute and rules.

BIO believes that in many cases, a well-designed and well-executed search will discover all relevant prior art for each of these embodiments. In addition, the patentability issues that govern the evaluation of the nucleic acid claim will likely be substantially the same as those that will have to be addressed with respect to an expression product claim. Similarly, issues that would have to be evaluated with respect to “generic” antibody claims are not likely to raise significantly different issues that will be evaluated in determining if either the sequence or its expression product can be patented. Moreover, it is not uncommon for applicants to also present claims to “downstream” inventions relative to those pertaining directly to the identified gene. Examples include antibodies with particular specificity or functional characteristics, new polypeptides that incorporate a portion of the sequence encoded by the gene in addition to other unrelated elements, or to methods of treating or diagnosing specific diseases or disorders. In each of these

examples, the prior art that may be discovered incidental to a well-designed and well-executed search for the first “inventive concept” will likely identify any prior art pertinent to these related inventions. Some additional searching may be necessary, but not to a degree that would impose significant burdens on the patent office.

Where a claimed invention raises substantially different patentability issues relative to a first claimed invention (i.e., a “related” invention), but would not indicate a substantially different search, the PTO should be able to charge an additional fee for examination of that invention. For example, some downstream inventions will present unique issues of patentability relative to those raised by the first inventive concept. Such issues may arise under one or more of sections 101, 112, 102 or 103 of U.S.C. title 35. Because of this, the downstream inventions are properly considered to be “related” inventions relative to the sequence/polypeptide inventive concept, for which the PTO shall be entitled to charge additional fees, and to provide examiners additional time to fully evaluate.

If a claimed invention requires both a new search and consideration of substantially different patentability issues, a higher fee, comparable to a full filing fee, would be appropriate. We note that the PTO could collect such a fee either by requiring restriction in these unusual cases or by imposing an additional set of fees if the additional unrelated invention remains in the same application.

The PTO should retain procedures that let applicants determine which aspects of an invention are examined in a first application. Thus, if the office finds that the examination of claims will require additional fees, the applicant should be afforded an opportunity to elect the related invention(s) to be examined and for which additional fees will be paid. We believe that “additional invention” surcharges must be proportional to the (average) examination resources required for the examination. In our view, a surcharge approaching the cost of filing a separate application for each additional invention would not be appropriate or justifiable.

Should the PTO consider changes to patent term adjustment?

No. Patent term adjustment (PTA) is an important safeguard against unexpected delays in prosecution that are outside the control of patent applicants. BIO believes that PTA must remain available, regardless of the prevailing restriction standard.

We appreciate that the PTO’s ability to meet the three-year pendency guarantee of the current PTA authority is inextricably linked to its examination efficiency and workload. We believe that adopting procedures that permit more related aspects of an invention to be examined in a single application, rather than split apart, will reduce the average pendency of all applications. By reducing the total number of applications, the PTO can realize improvements to its overall productivity. More specifically, provided that the size of the examining corps remains constant, having to examine fewer applications will reduce overall pendency. Additionally, increased fees paid by applicants to cover the added expense for the search and examination of the related inventions

should also cover the additional time spent on the case by the examiner. Therefore, no change in PTA is necessary.

We note that certain procedures suggested by the PTO in the Request for Comments expressly rely on the serial examination of inventions. Current procedures for restricting and then rejoining inventions in some applications also promote the sequential treatment of issues that could easily be treated together. The serial examination of inventions in a given application is inefficient, in our view, and unduly delays the patent grant. For these reasons, current rejoinder procedures, as well as concepts similar to those proposed in question 7 and 8 of the Request for Comments, seem inconsistent with the goal of expediting examination.

Issue 3 Should examination default to the first claimed invention under a unity analysis?

BIO strongly supports procedures that give an applicant the opportunity to elect the subject matter that will be examined in an application. We also realize, however, that protracted delays involved in formulating and responding to requirements for restriction impose administrative burdens on the patent office and undesirably increase the average pendency of applications.

Requirements for restriction based on related and unrelated inventions, like restriction analyses under the PCT unity-of-invention standard, are likely to be much more straightforward than restrictions under the independent-and-distinct standard. We therefore believe that much less time will be consumed by both the PTO and applicants to prepare and dispose of restrictions and elections under a unity-like standard.

We believe that it would be appropriate and practical to allow applicants a much shorter time in which to respond to restriction requirements under a new standard. For example, the PTO could set a one- to two-month, non-extendible period for response in which applicants could elect the invention(s) to be examined. Abandonment would not be a reasonable sanction for the failure of an applicant to respond within such a short period. However, if an applicant proved unwilling or unable to respond within the prescribed timeframe, it would be appropriate for the PTO to commence examination based upon the first-claimed invention.

We also note that if the PTO adopts procedures for automatically examining particular claims, applications filed before the change in practice should continue to be handled as they are today (i.e., applicants will be contacted to select the invention[s] to be examined).

Issue 4 Should the United States conduct a partial search where “unity” based only on prior art leaves broad claims that would be burdensome to examine?

BIO strongly opposes any standard that would allow the PTO to search and examine only part of a unitary invention. Where subject matter that arguably corresponds to several inventions is related, an applicant should have the option of claiming such

subject matter as a single invention, subject to the constraints of proper claim form. By the same token, the PTO should recover fees that reflect the resources required to examine the full scope of a group of related inventions, whether such inventions are presented in a single claim or in multiple claims.

Should a unity standard take patentability issues other than prior art into account?

Yes. Particularly in the biotechnology area, issues concerning patentability requirements other than novelty and nonobviousness must be thoroughly and accurately examined. As a result, the PTO should take into account issues under §§ 101 and 112 as part of its determination regarding the examining resources—and consequently the amount of the fees—that will be needed to thoroughly examine the application.

In this regard, we believe that the current PCT standard for unity of invention, which is based solely on the status of the claims vis-à-vis the prior art, is not suited to modern patent practice. Instead, the PTO should adopt a standard that differentiates between related and unrelated inventions based on the nature of the substantial patentability issues likely to arise during examination. Where several related inventions are claimed, the most efficient use of resources calls for examining all the related inventions at the same time. The applicant should have the option of electing one or more related inventions for concurrent examination, and the PTO should charge a differential fee that fairly reflects the resources consumed for each such related invention. Where unrelated inventions are claimed, the PTO should have the authority to either require restriction in the manner of current 35 U.S.C. § 121 or the payment of significant additional fees that reflect the additional work that must be performed to properly examine such an application.

Issue 5 Given that a unity standard would lead to fewer total applications and thus require the PTO to raise fees to support its operations, how should the fee increases be distributed?

BIO supports the current policy of maintaining low initial filing fees for all applicants. Such fees allow applicants to secure their patent rights from the outset at nominal cost, while affording them a reasonable length of time to assess whether an invention has sufficient commercial potential to merit the investment of time and resources to prosecute and maintain patents. We note that BIO's membership includes many academic institutions and small enterprises, for which high initial filing fees would present a substantial barrier to protecting intellectual property rights.

BIO members realize that the examination of some of their inventions is resource-intensive, and they accept the obligation to bear costs that fairly reflect the resources consumed in such examination. BIO believes that the most equitable way to assess such costs is through surcharges in connection with the examination of more than one related invention in an application. Such surcharges should apply only to fees incurred after the PTO has determined the number of related and unrelated inventions presented, and the applicant has selected the inventions to be prosecuted. Thus, it would be appropriate to

assess “related invention” surcharges to search and examination fees, but not to the issue and maintenance fees. If, however, the PTO requires more resources because of lost maintenance fee revenue from a change in current restriction practice, the maintenance fees should be raised in all technologies.

Issue 6 How should the PTO examine applications where unity of invention would require technical expertise in several disciplines?

BIO members have rarely encountered situations in which technical expertise outside Technology Center 1600 has been required or invoked in the examination of their applications. In fact, in the vast majority of cases, divisional applications in the biotechnology arts are assigned to the same examiners who handled the parent applications. The situation may be different in some other arts. BIO is not in a position to comment on the detailed solutions that will best serve applicants’ interests and the PTO’s operational needs in such situations.

As a general matter, BIO favors operational structures that encourage consultation between examiners whenever it will clarify issues, inform arguments or otherwise advance prosecution. We also favor mechanisms for fairly compensating examiners for the effort they expend in such consultations. BIO believes that the current examination model, in which a single person examines each application and communicates with applicants, remains the best starting point for organizing the deployment of examination resources.

Issues 7–8 Should the PTO explore a quasi-unity practice without new legislative authority by allowing rejoinder and examination of restricted independent-and-distinct inventions through a modified continued examination (RCE) practice?

No. We strongly oppose developing any serial examination model, including one based on the current RCE authority. Such a model would not address most of the critical problems that the application and misapplication of the “independent and distinct” standard have caused in present practice. Moreover, a serial examination model would allow applicants to improperly delay issuing patents for inventions that have been fully examined.

BIO believes that the efficient use of the PTO’s and applicants’ resources can be realized only by implementing new restriction standards that will permit and *encourage* the concurrent examination of related inventions in a single application.

Issue 9 Should the PTO seek amendment of 35 U.S.C. § 121, change its rules under existing authority or continue current restriction practice?

The PTO should seek amendments to 35 U.S.C. § 121 as the basis for changing its restriction practice. The current legislative authority that governs the PTO’s ability to manage its workload and collect additional fees for cases that present additional resource demands is not adequate. Moreover, the current authority simply does not address the needs of BIO members. Statutory changes that authorize the PTO to consolidate the

examination of various aspects of an invention are needed. Changes are also needed to authorize the collection of additional fees where several distinct aspects of an invention are examined in a single application.

BIO believes that statutory changes to enact standards consistent with our recommendations above would be desirable. Such changes should:

- permit the applicant to determine whether to file a divisional application or pay additional fees, rather than be subject to unilateral requirements regarding the procedures for examining the various claims presented; and
- allow the PTO to impose certain fees for examination of related inventions (i.e., those that present significantly different patentability issues, but do not need a significantly different prior art search), and to impose higher fees for consolidated examination of applications requiring both evaluation of significantly different patentability issues and additional searches.

BIO and its members stand ready to work with the PTO to devise appropriate legislative amendments to provide effective changes to restriction practice.

Issue 10 Other solutions

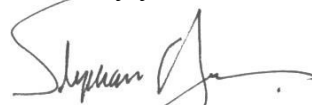
A revised “count” system is an essential component of any effort to re-engineer the restriction regime in the PTO. BIO’s interest in this issue involves more than the question of basic fairness to examiners. The production credit given for examining a particular set of claims provides an incentive that directly affects the amount of effort that will be invested in the examination. Every claim that is passed to issue should be thoroughly examined.

Moreover, counts are directly correlated with the way the PTO measures productivity. This measurement is central to tools the office uses to allocate resources internally and to the way it reports its output to Congress. The productivity metric, in turn, has implications for the way that pendency is measured and reported. It is essential that these fundamental metrics *proportionately* reflect the time and resources used to examine related inventions.

Conclusion

BIO and its members appreciate the opportunity to offer these comments.

Sincerely yours,



Stephan E. Lawton
Vice President and General Counsel
Biotechnology Industry Organization