From:
Sent: Saturday, February 13, 2010 8:29 PM
To: Kappos, David; Rai, Arti; Hirshfeld, Andrew
Cc: Josh Makower, MD
Subject: Follow-up regarding our meeting

Director Kappos, Administrator Rai and Deputy Commissioner Hirshfeld,

Thank you very much for meeting with us. Following up on your request regarding vignettes related to the criticality of timely patent determinations to our businesses we have prepared the attached summary. There is a link between patents and jobs in our small businesses. If there is other detail or additional information you need please feel free to contact us.

We are very encouraged by the actions you have taken to improve the Office. The change in attitude of examiners and their supervisors is noticeable. We are taking advantage of the PCT-PPH, pre-first action interviews and pre-appeal brief conferences. As I mentioned to Drew, we would like to take advantage of the backlog reduction stimulus plan but have concerns over the express abandonment requirement's effect in subsequent litigation or in explaining to investors or acquirers. If the requirement was a 5-7 year deferral, it would be more attractive. Most applications would likely lapse at the end of their deferral period.

We hope to have a continuing dialogue with you regarding possible other improvements (both administrative and legislative) and your initiatives. Josh is looking forward to Secretary Locke's workshop in a couple of weeks and hopes you will be in attendance.

If we can help advance your new initiatives, please feel free to contact us.

Sincerely,
Eb

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Dear Director Kappos,

We appreciate the opportunity to meet with you and your staff to provide suggestions on how to reduce the patent application backlog and enhance the quality of patents. We believe that your mission to improve the quality of the overall patent examination and prosecution process, to reduce patent application pendency, and to ensure that granted patents are valid and provide clear notice is extremely laudable and essential to the health of the patent system in the US.

Background

We are employs at three medical device company creators/incubators that have started and supported about 20 companies in the last 15 years. A patent system that provides **certainty** and **clarity** in a **timely** fashion of a patent holders rights are critical to the business decisions we make regarding what business opportunities are the right ones to pursue. It is also important in order for us to attract the high quality people and capital we need in order for the companies we create to be viable.

Having reviewed the recently released Request for Comments on the Enhancement in the Quality of Patents ("RFC"), we believe that the following recommendations are consistent with the goal of enhancing the quality of patents. These recommendations are rooted in the objectives of certainty, clarity and timeliness. While some of these recommendations may not meet the guidelines of achieving your goal of "without changes in the rules or laws or much increased expenditure", we believe that it is important to put all of our recommendations on the table to facilitate a full and open discussion and move toward the goal we all share. We believe that our recommendations do, however, provide practical suggestions of ways to obtain measurable outcomes.

Discussion

The RFC identifies seven categories for inquiry and four areas of particular interest. We have, in this memo addressed the following categories,

How should the office measure quality of the examination process as well as quality of the final product (issued or abandoned patent)?

> Measure robustness and quality of rejection, not breadth of claim. A first office action on the merits that includes a thorough analysis of the statutory factors and clear description of that analysis will bring all issues to the beginning of the prosecution process so that they can be dealt with in an efficient manner. Further, requiring examiners to truly provide a robust and clear explanation of their analysis will eliminate poor quality rejections that currently delay the prosecution process. Simultaneously, a robust and thoroughly documented prosecution process will give business decision makers certainty and clarity of the patent rights and avoid the ambiguities that lead to unnecessary litigation or frustration regarding poor quality patents.

What stages of the prosecution process should be most closely monitored for quality problems?

We believe that the key is to measure quality throughout the prosecution process (this will also be a valuable training aid for the Examiner's since they will be getting real time feedback). The most important stages are at the front of the process – application filing, interview, first office action, and examiner's response to applicant's first response. Robust actions at each of these time points will bring all the issues to the forefront and provide clarity so that timely, effective decisions can be made and the public notice function provides certainty to third parties.

Are there ways to reduce pendency while increasing quality? (How has the flux of continuations and RCE's impacted quality and pendency?)

Docket Visibility for Examiners and Applicants

Applicants currently feel compelled to cite every even remotely related patent application in their portfolio and even each office action received in such applications to be sure they will not later be accused by an accused infringer of violating their duty of disclosure. A system which provided the Examiners with visibility to all related applications and the prosecution history for each would allow the Examiner to easily review all the relevant actions and make his/her own decisions about what is relevant, while relieving applicants of this significant burden.

Make Examiners Perform a Full Graham Factors Analysis for Obviousness

Examiners routinely skip identifying the person of ordinary skill in the art or providing a rationale related to the references as to why they make the invention obvious. Requiring examiners to perform these steps will help to prevent hindsight bias because the analysis will be focused on the teachings of the art at the time of the invention rather than being grounded in the teachings of applicant's application.

Enhance and Empower the Examiner

- Train and allow examiners to:
- rely on prosecution history estoppel;
- come prepared and commit in interviews; and
- suggest patentable subject matter from the claims or the specification.

Improvements in Examiner Experience and Quality

We believe that there has been a clear drop off in the quality of office actions we are receiving and believe that it is imperative that the office improve examiner training and mentoring. In addition, we believe that allowing applicants and their representatives to participate in examiner reviews and contribute comments would enable examiners to see their work through Applicant's eyes and help them improve their performance.

Reducing Double Patenting Rejections

Examiners spend a significant amount of time and effort searching and reviewing files for the purpose of ensuring that Patentees are not granted multiple patents on the same invention or an obvious variation thereof. However, today this rational only applies to a very small and rapidly declining percentage of patents and the effort expended provides little or no benefit given the 20 years from earliest priority date limits that apply

to substantially all patents issuing today. We, therefore, believe that examiners should be relieved of the obligation to make these searches and issue these rejections. One option would be to request a terminal disclaimer in every prosecution and conduct the search only if the Applicant refused to enter the terminal disclaimer.

Eliminate the Requirement for Applicant to Cite Patent Literature

Patent examiners are generally better than applicants in finding the most relevant patent literature. Applicants are generally better than examiners in finding the most relevant non-patent literature. Eliminating the applicant "dumping" a bunch of patent references on the examiner will allow each party to focus on the most relevant prior art references. Applicant will still provide the patent references that are the most relevant in their mind because they want a valid and strong patent and the reduction in the amount of overall information that is provided will allow the examiner to use the hours he/she has allotted to focus on the most relevant non-patent and patent references. (See more discussion below in the Prior Art topic).

What pilot programs are working: Peer-to-Patent; Pre-Appeal Brief Conference; First Action Interview; CLE for Practitioners? Ideas for pilots?

Expediting Examination and Reducing Backlog

Various mechanisms have been proposed by the PTO and others for increasing the speed of examination and reducing the backlog of patent applications awaiting examination. While many would like to see a substantial enhancement of the PTO's budget to enable it to hire more examiners and build the infrastructure for faster processing, this is unlikely to happen in the near term. However, significant improvements could be made simply through more efficient and targeted use of existing PTO resources. Possibilities include offering the options of expedited or deferred examinations, or implementing a cap-and-trade-like system for prioritizing patent applications. In addition, alternative forms of IP protection involving less time-intensive examination could be offered to applicants who do not require the full rights and benefits of a utility patent.

Modified Expedited Examination

The biggest impediment to Applicant's and particularly entrepreneurs to using the current expedited examination process is the cost and potential litigation traps involved in preparing the initial search report. We have estimated that preparation of that search report could exceed fifty-thousand dollars ($50,000.00) per application. The analysis required of the applicant opens the issued patent up to significant second guessing, estoppels and inequitable conduct arguments in any subsequent litigation. The result is that we rarely use the current expedited examination process. A modified Expedited Examination that required only the payment of a fee would be beneficial to the applicant and, depending upon the result, might convince the applicant that pursuit of other related or co-pending applications would not be fruitful, reducing the burden on the Examining Corps. The fees for such expedited examination could be set at a level that offset the added costs to the PTO. And to further offset any added workload, in return for such expedited examination of one application, applicants could be required to

accept deferred examination of one or more other applications in their portfolios (see below).

Deferred Examination

Many times the value of an application or invention is unclear, even to the inventor at the time of filing but, because there is no deferred examination procedure available in the US (Japan and Korea both have such procedures), the inventor is required to or pursue the invention as if it was of great value as soon as it comes up for examination. Giving inventors the option of paying a fee to defer examination would provide inventors with the time to determine the true value of the invention before requiring the Examining Corps to examine the application. Inventors would likely abandon marginal or valueless applications before they were examined, reducing the burden on the Examining Corps.

C. Cap and Trade

PTO resources should be allocated more heavily toward those applications valued highest by applicants so as to cut the pendency of only the most highly valued applications. Cap-and-trade principles can be readily applied to meet these objectives. Such a system might be structured as follows:

- Annually the PTO would issue a fixed number of "fast-track permits" to each filing entity based upon that entity's total filings that year (e.g. 25% of filings). This forms the "cap" on the overall number of filings that are to be expedited.
- A fast-track permit would entitle the holder to receive expedited examination of one patent application. The PTO would guarantee examination within a certain period after filing, e.g. 12-18 months.
- Patent applications not expedited by means of a fast-track permit would be prioritized lower than those with a permit. The PTO would examine these at whatever pace it could afford. In the short term it would be expected that such applications would have longer pendency than the present average, although with increases in capacity and efficiency, it would be reasonable to expect that these applications could eventually be processed faster.
- Instead or as a condition of a per-entity quota of fast-track permits, the PTO could allow entities to trade deferred examination of certain applications in return for fast-track permits. For example, two deferred examinations could be traded for one fast-track permit.
- Optionally, fast-track permits could be freely tradable among filing entities and could be sold for value, allowing entities that have less need for fast processing to sell their permits to others who need it.
- Optionally, the PTO could sell or auction off additional fast-track permits to generate revenue that would pay for any added examining corps capacity required for faster processing.

Alternative Forms of Protection

Utility Model

A utility model application would result in a Utility Model or Petty Patent similar to those available in countries such as France, Germany and Japan. Current applicants who have applications waiting for examination could pay a fee to elect t convert to a utility model, thus generating PTO revenue now and reducing the number of applications awaiting examination. Of course, the details would have to be worked out but the resulting Patent could have a limited term (e.g. 10 years) and no presumption of validity. There would be little or no examination beyond formalities, thus limiting the burden on the Examining Corps.

Limited (102/112) Examinations

Applications would be examined for 112 written description, enablement, double-patenting and 102 novelty only. The resulting patent would not be entitled to any presumption of validity on obviousness. The limited examination and simplicity of 102 would likely result in a very compact prosecution, limiting the burden on the Examining Corps and, potentially creating a training ground for new Examiners. Current applicants could elect to convert to this limited examination.

Are there specific tools (software, processes, etc.) that the PTO should be using to increase quality?

Application Quality Software

Make it a requirement for the filing of a non-provisional patent application for the applicant to use software such as Claim Master http://www.patentclaimmaster.com/ prior to filing the application. This type of software will increase the quality of the application at the beginning of the process and eliminate the time wasted by examiners on issues other than patentability under 102 and 103.

Doctrine of Equivalents

Changing the law to reinstate the doctrine of equivalents for amended claim elements (legislatively overrule Festo) could substantially decrease the current backlog. Applicants are currently incentivized to pursue multiple patents that are very close in claim scope because any prosecution amendments limit their ability to enforce the resulting patent. Therefore, under current law, applicants are incentivized to generate a cloud of patents or maintain multiple continuation/divisional applications to ensure that they have an opportunity to write claims which are literally infringed prior to asserting a patent. We therefore advocate legislation which overrules Festo to allow an applicant to receive a range of equivalents for their amended claims (subject to prosecution history estoppel). We believe this will result in the pursuit of fewer continuation and divisional applications and reduce the need to keep an application family pending throughout the life of a product.

Obviousness

The KSR decision has effectively handed examiners a license to reject a claim for whatever reason they choose. In the eyes of an examiner, who almost always lacks deep

expertise in the field of the subject invention, and who has no choice but to look at the invention with the benefit of hindsight, anything may seem obvious, especially if various references have been found that are close but not exactly the same as the subject invention. However, it stretches the imagination to suggest that making a combination of teachings is "common sense" even though no suggestion to do so has ever been published in any form. In any event, such rejections which lack any identified teaching, suggestion, or motivation in the prior art should be the exception rather than the norm. This is particularly true in medical devices and other technologies within the life sciences where the application of mechanical, electrical, biologic, or pharmaceutical inventions to human beings creates substantial uncertainty as to the effect and/or outcome. Simply because a particular technology worked in one part of the body to treat a certain disease by no means suggests that it will work in a different part of the body on a different disease. Thus, to the extent the KSR decision eliminates the requirement on an examiner to identify a teaching, suggestion, or motivation for combining the teachings of prior art references, then KSR should be legislatively overruled. Until that occurs, we believe the guidelines for obviousness rejections should be modified to clarify that in almost all cases examiners should be expected to identify a teaching, suggestion, or motivation in the prior art, and only in exceptional cases would something be so "common sense" that it would excuse that requirement. Further, even in these exceptional cases, the examiner should be required to identify with particularity detailed reasons why common sense suggests the combination and overcomes all of the uncertainty that the combination would work. We would also like to see such new guidelines take into account the unpredictability of certain arts, particularly the life sciences.

Particular Interest Topics in the RFC

Prior Art: How to identify the "best" prior art in ways that it can be used by an examiner.

Reducing the Duty of Disclosure Burden

We believe that the duty of disclosure should be modified to eliminate the requirement of citing US patents and published patent applications to the patent office. This requirement, combined with the threat of an inequitable conduct assertion in litigation, has degenerated into the routine practice of citing huge numbers of patents and patent applications however remotely related to the subject application, creating a mountain of prior art in which are buried a few truly relevant pieces. This fails to improve patent quality nor does it help the examiner identify the closest art. Examiners have sophisticated tools for patent searching and are adept at reviewing patent documents. The examiner cannot reasonably process a mountain of information submitted by the applicant in the time they are allotted for an application and is still likely to perform his own search. The current disclosure requirement may actually reduce patent quality in that the most relevant art is submitted among hundreds of other documents, making it unlikely the examiner will identify it but still allowing the applicant to enjoy the presumption of validity over it. Meanwhile, the requirement creates significant burdens for applicants while providing infringers with fodder to conjure up meritless inequitable conduct defenses.

Modifying the PTO's rules to only require applicants to submit non-patent literature while leaving in place the duty of disclosure regarding material information has several advantages. The examiner will focus their searching time on the patent literature that they have the better expertise in finding. Applicants will be supplying non-patent literature which they are better at finding. Also, Applicants being shielded from hindsight allegations of inequitable conduct for patent literature will be supplying only the most relevant patent literature under their duty regarding material information but will not flood the examiner with much less relevant references. Examiners will be able to more efficiently use their allocated time based on this small set of most relevant prior art.

Higher Quality Patent Applications: Are there ways that the USPTO can help (or push) applicants to write better applications that do a better job of describing the invention and that include claims in the initial application that actually take the prior art into consideration?

Patent Office Provide a Search with Simple Opinion Ratings

Require before the filing of a non-provisional application (unless foreign originating) that the Applicant provide a one paragraph summary of their invention and up to 10 claims (and optional drawing) to the Office for searching at a low price. The Office will provide the applicant with a simple list of references that are identified as simply X, Y or A (similar to a PCT search report). This process could be required for all applications or it could be incentivized by granting Special Status to applicants who use this process prior to starting the examination process.

Interviews: **How should interviews be used in a way that improves quality and pendency?**

Binding Interview Process.

The lack of a binding interview process is a serious impediment to the use of the interview process. In many applicants' experience the interview process is not as effective as it could be because it rarely results in an allowance, even when the Applicant and Examiner agree that the art of record should not prevent the issuance of the pending claims. More often than not we find that examiners appear at interviews unprepared without having reviewed the art of record or applicant's arguments, apparently viewing their obligation as merely to listen. Because interviews have no binding effect on the examiner, s/he has no incentive to prepare adequately for the interview or to fully debate the issues to a resolution that s/he can stand behind. In order to address this problem, it is suggested that examiners be precluded from issuing rejections on art already of record in a case after an interview which results in agreement on patentable claim language. Another potential way to address this issue is to reduce the number of points given to examiners for office actions issued after a successful interview or an action based upon previously cited art. If the applicant has submitted proposed claims to the examiner in advance of an interview, the examiner should be required to perform any searching related to the new claim language in advance of the interview. In addition, the applicant should have the right to have the supervising examiner attend any interview. The PTO

could also offer the option of a formal binding interview by payment of a fee after a first office action on the merits has been issued. The applicant would be required to submit any proposed new claim language in advance and the examiner would be required to perform any searching in advance of the interview. The outcome of the interview would be either a final rejection or an allowance based on the art already of record.

Earl Bright Jeff Grainger

ExploraMed

ExploraMed's primary mission is to significantly improve the quality of life for patients through fresh paradigms. ExploraMed is a venture-backed medical technology incubation company dedicated to the identification, creation and development of new medical device solutions. We create new ideas which match certain key fundamental criteria and add capital, intellectual property, and expertise in the fields of clinical, engineering, legal, strategic marketing, and financing, while focusing on efficient and timely development. We form new companies, hire a management team and obtain financing to bring these new technologies to patients.

ExploraMed's key financial partner is NEA, one of the largest venture funds in the country. NEA has been helping to build great companies since 1978. Their committed capital has grown to approximately $8.5 billion and has funded more than 550 companies in the IT and healthcare sectors. Most notably, intellectual property plays a fundamental piece of their review before considering an investment – and nowhere is that more true than for their healthcare sector. Given the tremendous amount of capital required to develop and launch a company in the healthcare space, if the patents underpinning the company were not believed to be broad and powerful, NEA would not consider them a viable investment.

ExploraMed I, founded in 1995, created two medical device companies, EndoMatrix Inc., and TransVascular Inc. ExploraMed II, founded in 2004, produced two new businesses, Acclarent, Inc. and NeoTract, Inc. ExploraMed III, founded in 2006 has produced Vibrynt, Inc., and Moximed, Inc. Each of these created companies has a foundation built upon patentable technology that has enabled them to hire employees and contract with many supporting organizations such as contract manufacturers, clinical research organizations and engineering consultants. The patentable foundation is so important that it has played a significant factor in either the companies acquiring rights or being acquired because of rights.

Companies Created

Acclarent, Inc. (founded in 2004) is focused on developing several new technologies in the field of Ear, Nose and Throat Surgery (ENT). It is currently commercializing its Balloon Sinuplasty™ technology with manufacturing in the United States. Acclarent employs about 300 people and was acquired by Johnson and Johnson/Ethicon in January 2010. Acclarent's products have been used to improve the quality of life of over 100,000 chronic sinusitis patients. Acclarent

has developed a portfolio of over 100 patents and applications. The investors in Acclarent have placed a strong emphasis on intellectual property throughout the company's history. Acclarent's expansion into new fields within ENT has been built around in-licensing and acquiring patents and applications from individual doctors and small companies. It would not have expanded into these additional fields without a strong IP foundation. Acclarent has also witnessed the unfortunate effects of the Patent Office's backlog. It took approximately 4 and ½ years for Acclarent's first patents to issue which is about 3 years after Acclarent began selling its products to doctors. During the approximate 3 years it took to receive a first office action, other companies not sure of the boundaries of Acclarent's IP began to develop and commercialize similar technology. Those company's development activities could have been directed to other technologies that would have brought improved quality of life for patients had they known earlier the boundaries.

Moximed, Inc. (founded in 2007 has raised about $22 million in financing) created a new device to address osteoarthritis. It is in the clinical development phase and is beginning to commercialize its technology in European markets with manufacturing in the United States. Moximed employs about 25 employees and indirectly employs contract manufacturers, clinical research organizations and engineering consultants. Moximed has developed a portfolio of about 30 applications and 3 patents including acquiring patents and applications from Imperial College (which first patent from the acquired applications is set to issue shortly; about 6 and ½ years after its filing). Moximed's first 3 patents issued about 2 and ½ years after their filing. This patent foundation will enable Moximed to secure the financing it needs to employ the workers to conduct its clinical trial in the United States and manufacture products for sale in Europe. These timely issued patents also will provide clarity to others regarding the boundaries of Moximed's intellectual property.

NeoTract, Inc. (founded in 2004 has raised about $45 million in financing) created a novel approach for treating an enlarged prostate. NeoTract employs about 30 employees and indirectly employs contract manufacturers, clinical research organizations and engineering consultants. It is in the clinical development phase and is beginning to commercialize its technology in European markets with manufacturing in the United States. NeoTract has created a portfolio of about 25 applications and 1 patent so far. There was a delay of 3 and ½ years and 3 years, respectively, for its first two filed patent applications. Because of the delay, the uncertainty regarding the scope of NeoTract's IP was a significant issue in raising a new round of financing. With the issuance of it's first patent (over 4 years after its filing), NeoTract can secure the financing it needs to employ the

workers to conduct its clinical trial in the United States and manufacture products for sale in Europe.

Vibrynt, Inc. (founded in 2006 has raised about $45 million in financing) focused on the field of obesity, is currently in the clinical development phase with manufacturing in the United States. Vibrynt employs about 30 employees and indirectly employs contract manufacturers, clinical research organizations and engineering consultants. Vibrynt has developed a portfolio of about 25 patent applications including in-licensing patent applications from Louisiana State University (LSU). It has taken over 3 years to receive a first office action on the merits in Vibrynt's first filed application and the first action prediction for the LSU application is currently at 4 years after its filing date. As Vibrynt establishes the clinical effectiveness of its novel obesity therapy, it is going to be very important that it can demonstrate the strength of its intellectual property in order to secure the financing needed to hire employees for conducting its clinical trial in the United States.

EndoMatrix, Inc. (founded in 1996) was created to develop a novel approach for tissue bulking in incontinence and GI reflux. EndoMatrix employed 6 people and was acquired by C.R. Bard, Inc. in 1997 primarily for its intellectual property.

TransVascular, Inc. (founded in 1996) was created to develop several novel revascularization technologies including percutaneous coronary and peripheral bypass and cell injection technologies for cardiac regeneration. Transvascular employed 45 people and was acquired by Medtronic, Inc. in 2003. TransVascular's products have improved the quality of life of thousands of patients. Medtronic placed tremendous value on TransVascular's patent portfolio of about 65 patents and patent applications, particularly with respect to its needle injection catheter. In fact, Medtronic has since out-licensed several components of TransVascular portfolio to start-up companies and this IP has proved to be a valuable strategic asset for them.

Summary

The stories above are a brief description of the importance of patents to the existence of our companies in the United States and more importantly to the lives of the patients that benefit from the new therapies. As you can see in the stories above, there are positive and negative examples but what they have in common is the importance of the timely determination of the scope of the patent rights. We would be happy to expand on any of these stories if that would be useful to you. We support you in the steps that you have taken to bring about an improvement in

the patent application process. We believe that the budget for the Patent Office must be increased to facilitate the timely issuance of quality patents. We support eliminating fee diversion and granting the Patent Office the authority to establish new fee based programs that enable first office actions on the merits within 18 months of filing. Please let us know if there is anything we can do to help achieve your objectives.

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