



Pfizer Inc. is pleased to make the following submission to the President-Elect's Transition Team.

Pfizer invests billions of dollars annually in R&D activities to bring to market innovative medicines that improve and enhance the lives of hundreds of millions of people in this country and around the globe. The pharmaceutical industry, far more than most industries, is critically dependent on the existence of strong patents to foster and protect the next generation of innovative drugs. Without the guarantees of strong and predictable patent protection, financial investment in the development of new drugs will be in serious jeopardy. Large companies like Pfizer also in-license and develop technology/medicines from small companies, start-ups and universities whose success is also dependent on investment capital that relies on a well-functioning IP protection system. We believe transformation of the USPTO is crucial to address the significant backlog of pending applications and concerns on the quality of patents. To achieve this, we suggest the following:

- The PTO has serious problems with administrative delay in examining and granting patents. The solution is not further delay, deferral or postponement of examination of pending applications, which would exacerbate an already intolerable situation. If companies are to make investments in new products they need clarity on the IP/patent landscape prior to proceeding at the substantial financial risk of infringement. Delayed or deferred prosecution of patent applications permits applicants to *ex post facto* disrupt the IP landscape at a time substantially after companies have spent many tens or hundreds of millions of dollars and to upset investment expectations made at a time when the IP situation was clear.
- A first solution to these disturbing delays is to increase funding for training/hiring of technically competent Examiners. This can be funded via allocation of the user fees that are already paid by patent applicants into the PTO. The fees that enter the PTO should not be diverted to other branches of government unless and until the obligations of the PTO to provide rapid and competent examination have been met. A system of enhanced Examiner compensation, training and retention initiatives would be beneficial here.
- A second suggestion goes more to the process issues of how and when the PTO deals with pending applications. The PTO should review current Restriction Practice (the manner in which the PTO divides up the number of inventions in a filing) which regularly results in dozens of applications being spawned out of a filing (contrary to the practice in other countries) and resulting in further glut of applications on the books. This problem is particularly acute in biologics/biotechnology, the most promising area for new medicines, where PTO inexperience and rigidity promulgates costly delay. Examiner interviews with patent applicants at certain times (such as pre-search and pre-first-action interviews) could be used to dispense with much paperwork that arise from miscommunications.
- A third suggestion is to reform the Patent Examiner Production System, i.e, the amount of time an examiner receives to appraise an application. While necessary to ensure efficiency, the current system may be improved by adjusting goals so more time is given for a first case review, taking advantage of searching and examination conducted by other patent offices, and providing adequate time after final rejection to consider amendments and evidence.
- A fourth suggestion is to further the work that has already been undertaken with the European and Japanese Patent Offices to share examination burden and search results.
- The next Director of the PTO must be someone who clearly understands IP and its relationship to the health of the US economy and US innovation. The new Director should have the following qualifications: 20 plus years of experience as a practicing patent attorney; at least 10 years of experience managing a business or division thereof; the ability to effectively and diplomatically represent US interests in international negotiations; the ability to effectively work with both Congress and Executive branches; experience in building consensus and fostering cooperation amongst the major patent interest groups (e.g., AIPLA, IPO, ABA); and the vision and talent to improve the operations and work-product of the USPTO.