process for creating the plasmid itself".[1161] By contrast, the court concluded, the patented process in *Bayer* is not used in the actual design of the drug. As the lower court had noted "processes of identification and generation of data are not steps in the manufacture of a final drug product."[1162] Thus, the Court concluded that the product of *Bayer* does not fall under Section 271(g).[1163] Infringement under Section 271(g), the court explained, is limited to the manufacture of physical goods. It does not extend to knowledge that is generated by a patented process. Therefore, the Court stated that the dismissal of Housey's claims of infringement of patents covering methods of screening compounds that have particular characteristics must be affirmed.[1164] In sum, the reasoning set forth by U.S. courts resembles the situation existing under the EPC and the GPA.[1165] Patents to screening processes do not extend to compounds identified by these screening processes.

## VIII. Concluding Remarks

The foregoing shows that patent owners who often find themselves in an interdependent relationship, are able to balance their interests through cross-licensing agreements.[1166] This applies with regard to selection inventions where the broad

1161 Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553, 1561 (Fed. cir. 1996); Bayer v. Housey, 340 F.3d, 1367, 1377-1378.

1162 Bayer AG, 169 F. Supp 2d. at 331; Bayer v. Housey, 340 F.3d 1367.

1163 Liebert, Mary Ann, Information is not physical goods, 22 Biotechnology Law Report 2003, 619-620. The Housey patents were rendered invalid in Housey v. AstraZeneca, 366 F.3d. 1348: Housey sued AstraZeneca alleging infringement of its four patents to screening methods related to protein inhibitors and activators. The district court construed the definition of "inhibitor or activator" to include substances that both directly and indirectly affect a protein of interest. Housey then stipulated that, if this construction were not reversed or modified on appeal, its patents would be invalid and not infringed. The district court came to a final judgment of invalidity and non-infringement. The Federal Circuit held that the claim construction of the district court regarding the "inhibitor or activator of a protein" was properly concluded and thus affirmed the decision. Consequently, the Housey patents were affirmed as invalid and not infringed. One judge (Newman) dissented. Housey, 366 F.3d 1348, 1349.

1164 Bayer v. Housey, 340 F.3d 1367, 1378.

1165 Chapter 4 C VII 1.

1166 Another mechanism by which companies may achieve synergies is the creation of patent pools. This practice allows companies practicing related technologies to assign or license their patents and establish a "clearing house for patent rights", Sung, Lawrence M./Pelto, Don J., The Biotechnology Patent Landscape in the United States as we enter the New Millennium, 1 The Journal of World Intellectual Property 1998, 889-901. In exchange for access to a patent pool, patentees retain their respective patents and license them non-exclusively to others. Licensing is made either directly or through an administrative intermediary created for the purpose. Patent pools are subject to close scrutiny for possible anti-trust violations and therefore must demonstrate that they have strong 'pro-competitive' effects. OECD, Genetic Inventions, Intellectual Property Rights and Licensing Practices, Paris 2002, 66.

claim typically dominates selective improvement.[1167] With regard to identified compounds, patent owners of the screening method can either try to agree on reach-through licensing agreements or – a safer method – determine other means, such as milestone payments.[1168]

A different case arises if the use of 3-D protein structures infringes the patent related to the underlying genetic information. As the above analysis has shown, this occurs provided the protein is obtained recombinantly. As soon as the native protein is used, no dependency is established. This result, having been achieved by an application of traditional legal standards, seems to establish a strong position for the owner of patents related to recombinant technologies. However, the practice of native protein purification recently has undergone tremendous advances.[1169] Hence, novel purification systems that enable the receipt of sufficient protein amounts and quantities might release inventors from the dependency upon earlier issued recombinant protein patents in the near future. Furthermore, protein research that is based on recombinant proteins in many instances will be covered by the research exemption in both the U.S. and Europe.

As for the patents on human gene sequences already issued, it is worth noting that the time factor will provide release of a potential blocking danger. The development of new drugs based on proteomic related knowledge is a time-consuming process. With a patent only providing 20 years of protection (Art. 63(1) EPC), most existing patents will expire before the time drugs based on proteomic research begin to be commercialized on the market. Until then, the research exemption provided under German law[1170] will ensure that researchers adequately proceed with their work.

Advances in the understanding of the complicated patterns of protein folding raises afresh the issue of competitive protein variant use. The awareness that the 3-D structure dedicates the function, rather than the sequence, may mobilize competitors to use sequence-dissimilar proteins bearing same folds, function and effects. To protect inventors from such uses, traditional legal standards developed in the field of protein variants must be modified. Previously, patentees used percent identity approaches with the sequence as reference in order to achieve protection from protein variants. To expand the patent scope to sequence-dissimilar proteins, the sequence reference should be replaced by a reference to the 3-D folding type. In addition, a claim to amino acids may be expanded to sequence-dissimilar proteins conducting the same functions under the doctrine of equivalents. In the U.S., the 'triple-identity-test' is considered an adequate means for the determination of equivalents. This approach requires that persons skilled in the art consider a means equivalent by its 'function', its 'way' and its 'result'. Applied to protein 3-D structures, an equal fold-

1167 Maynard, John T./Peters, Howard M., Understanding chemical patents: a guide for the inventor, Washington, D.C. 1991, 87; assuming that the selective part is the commercially most desirable product.

1168 See Chapter 3 B III 3 c) aa).

1169 Chapman, Tim, Protein purification: Pure but not simple, 434 Nature 2005, 795, 795.

1170 § 11 Nr. 2 GPA.

ing structure satisfies the 'way-prong' of the inquiry. A protein bearing a different fold, by contrast, is interpreted to conduct a function differently. In Germany, the country that is used as example for Europe, established principles require the presence of a technical effect identical *and* predictable for a person skilled in the art. The folding type is interpreted as a modified means. A skilled person must rely on all information provided by a patent in a step-by-step fashion and be able to predict which proteins are members of the same structural type. Due to the legal limitations of the doctrine of equivalents and the significant level of complexity required for a determination of equivalents, it is, however, not always predictable as to whether equivalents can be established or not. With this overall uncertainty, inventors might seek broad literal coverage rather than rely upon the doctrine of equivalents.