UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
BOSTON DIVISION

CARIS MPI, INC., Plaintiff, v. FOUNDATION MEDICINE, INC., Defendant.	C.A. No. 1:17-CV-12194 **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Caris MPI, Inc. ("Plaintiff" or "Caris") brings this Complaint for patent infringement against Defendant Foundation Medicine, Inc. ("Defendant" or "FMI"). Caris alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 8,880,350; 9,372,193; 9,383,365; 9,092,392; and 9,292,660 (collectively, "the Asserted Patents") under United States Patent Laws, 35 U.S.C. §§ 1 *et seq*.

2. Caris brings this action against Defendant because of Defendant's infringement of Caris' valuable patent rights.

THE PARTIES

3. Caris MPI, Inc. is a privately held corporation existing under the laws of the state of Texas and doing business as Caris Life Sciences. Caris MPI, Inc. has its principal place of business at 750 West John Carpenter Freeway, Suite 800, Irving, Texas 75039.

4. Caris is a pioneer and leading developer and provider of molecular profiling to aid physicians' selection of cancer treatments. Through its Caris Molecular Intelligence® product, a comprehensive genomic profiling product formerly known as Target Now®, Caris has provided molecular profiling for more than 123,000 clinical cases.

5. On information and belief, Foundation Medicine, Inc. is a Delaware corporation having its headquarters and principle place of business at 150 Second Street, Cambridge, Massachusetts 02141. On information and belief, Foundation Medicine, Inc.'s registered agent is The Corporation Trust Company, Corporation Trust Center 1209 Orange St., Wilmington, Delaware 19801.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* This Court has subject matter jurisdiction over Caris' patent infringement claims under at least 28 U.S.C. §§ 1331 and 1338.

7. This Court has personal jurisdiction over Defendant because, on information and belief, Defendant continuously, systematically, and purposefully conducts business within this District, including but not limited to making, using, selling, offering to sell, and/or importing the FoundationOne®, FoundationOne® Heme and FoundationACT® Products. Defendant has purposefully availed itself to the privileges and benefits of the laws of the state of Massachusetts by maintaining its headquarters in Cambridge, Massachusetts.

8. Venue is proper in this District under at least 28 U.S.C. § 1400(b) because Defendant has, on information and belief, committed acts of infringement in this District and has a regular and established place of business in Cambridge, Massachusetts.

FACTUAL BACKGROUND

9. Drug therapy for cancer patients has long been a challenge. Before the invention of the Asserted Patents, when a patient was diagnosed with cancer, a treating physician would typically select from a defined list of therapy options conventionally associated with the patient's observable clinical factors, such as type and stage of cancer. As a result, cancer patients generally received the same treatment as others who had the same type and stage of cancer. Efficacy of such treatment would be determined through trial and error because patients with the same type and stage of cancer often respond differently to the same therapy. Moreover, when patients failed to respond to any such "one-size-fits-all" treatment, either immediately or when a previously successful treatment began to fail, a physician's treatment choice would often be based on anecdotal evidence at best.

10. While not widely utilized at the time, limited molecular testing was available to aid the physician in making a more informed selection from the list of conventional therapies associated with the patient's type of cancer, also known as "cancer lineage." For example, a physician with a breast cancer patient, presented with a list of conventional therapy options including Herceptin®, could have tested the patient's tumor for overexpression of the gene HER2/neu. HER2/neu was known at that time to be associated with breast cancer and responsiveness to Herceptin®. For a portion of breast cancer patients whose tumor was found to overexpress the HER2/neu gene, the physician would have at least some indication that the patient may have an initial response to treatment with Herceptin®. While this type of molecular testing helped explain why a known treatment for a particular type of cancer was more effective in treating some patients with that type of cancer than others, this testing did not identify or exclude any additional therapy options for patients.

11. Dissatisfied with the one-size-fits-all approach to treating cancer patients, and faced with the reality that many patients' tumors progress and eventually exhaust all conventional therapies, Dr. Daniel Von Hoff, an oncologist, sought to identify additional, unconventional treatment options for his patients. He recognized the limitations of making treatment decisions based on clinical observation and the limitations of the few lineage-specific molecular tests available at that time. He believed that effective treatment options were overlooked because of these limitations.

12. Dr. Von Hoff teamed up with Dr. Robert Penny, a pathologist who was also a pioneer in molecular science, and together they identified "a need for determining an individualized medical intervention for a disease state based on molecular profiling that is used to target specific genes and/or gene expressed proteins with specific drugs or agents that is independent of disease lineage diagnosis." (Ex. 1, '350 Patent, at 2:28-33.) They invented and patented a novel system of performing molecular profiling of tumors to identify treatment options independent of cancer type, based on groups of molecular targets not traditionally or conventionally associated with a specific type of cancer. They recognized that "[i]f a larger number of targets or molecular findings such as molecular mechanisms, genes, gene expressed proteins, and/or combinations of such were measured in a patient's tumor, one may find additional targets or molecular findings that can be exploited by using specific therapeutic agents. Identifying multiple agents that can treat multiple targets or underlying mechanisms would provide cancer patients with a viable therapeutic alternative to those treatment regimens which currently exist." (Ex. 2, '392 Patent, at 2:11-20; *see* Ex. 1, '350 Patent, at 2:17-27.)

13. The patented system of molecular profiling uses various testing techniques to gather molecular information from a patient's tumor to create a unique molecular profile

independent of the type of cancer. In this way, the molecular profiling can potentially identify treatments for the patient's tumor that would not conventionally be identified as a treatment option, or expected to work, for that particular type of cancer. The physician can then use the results of the molecular profile to aid in selection of a candidate treatment for the patient regardless of the stage, anatomical location, or anatomical origin of the cancer cells. (Ex. 2, '392 Patent, at 135:10-12.)

14. By utilizing the patented system, new uses of known drugs can be found in the field of cancer treatment. For example, U.S. Patent No. 8,880,350 ("the '350 Patent") utilizes the molecular targets EGFR, KIT, TOP1, MLH1, PTEN, PDGFRA, and ESR1. This combination of molecular targets was not associated with a particular type of cancer. By utilizing this combination, the '350 patented invention yields treatment options for cancer that were not previously utilized.

15. The same is true for the combinations utilized in U.S. Patent Nos. 9,372,193 ("the '193 Patent") and 9,383,365 ("the '365 Patent"). Each of those combinations utilized by the claimed systems yields new, nonconventional treatment options for cancer that were not previously utilized. (*See* Ex. 3, '193 Patent; Ex. 4, '365 Patent.)

16. In addition to being useful broadly for cancer, Caris' invention can be utilized very specifically for particular types of cancer. For example, the '392 Patent utilizes the molecular targets BRAF, EGFR, PIK3CA, and PTEN in the context of treatments for colorectal cancer. At the time of the invention, at least BRAF, PIK3CA, and PTEN were not conventionally associated with treatments for colorectal cancer, and BRAF, EGFR, PIK3CA, and PTEN had not been used in combination to identify treatments for colorectal cancer patients. By using this combination in Caris' patented system, new treatment options for colorectal cancer can be

identified. (*See* Ex. 2, '392 Patent.) Similarly, U.S. Patent No. 9,292,660 ("the '660 Patent") utilizes the molecular targets BRAF, CTNNB1, cKIT, PIK3A, and PTEN in the context of treatments for lung cancer. At the time of the invention, at least CTNNB1, cKIT, PIK3CA, and PTEN were not associated with treatments for lung cancer, and CTNNB1, cKIT, PIK3CA, PTEN, and BRAF had not been used in combination to identify treatments for lung cancer patients. By using this combination in Caris' patented system, new treatment options for lung cancer can be identified. (*See* Ex. 5, '660 Patent.)

17. Caris' inventions also aid physicians in eliminating therapies that might otherwise have been used that will not be useful for the particular patient. This guidance saves patients from needless suffering and, perhaps more importantly, allows physicians to maximize the chances of a successful therapy in patients who often are in a race against time.

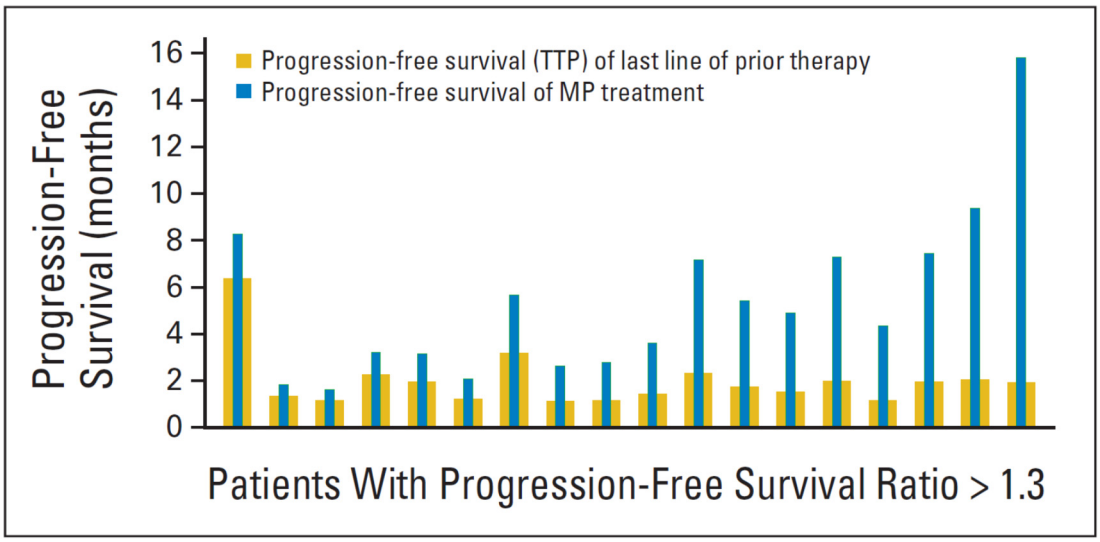
18. All these results are provided to the treating physician in a molecular profiling report, which the treating physician may then use to develop a personalized treatment plan for the patient. In this way, the treating physician can select treatments that are most likely to help patients based on a molecular understanding of their disease.

19. Dr. Von Hoff and Dr. Penny, along with other colleagues, conducted a prospective multi-center study to compare the progression-free survival (PFS) using a treatment regimen selected by molecular profiling of a patient's tumor with the PFS for the most recent regimen on which the patient had experienced progression.

20. The results of this study were published in the Journal of Clinical Oncology on November 20, 2010, in a report titled, "Pilot Study Using Molecular Profiling of Patients' Tumors to Find Potential Targets and Select Treatments for Their Refractory Cancers" (hereinafter, "2010 Pilot Study"). (Ex. 6, 2010 Pilot Study.)

21. The 2010 Pilot Study found that 27% of the patients treated according to the patented molecular profiling techniques had progression-free survival of at least 30% longer than they had on their last prior therapy (a PFS ratio of ≥ 1.3). Of those patients, the median PFS ratio was 2.9 and the maximum PFS ratio was 8.15.

22. The following chart shows the comparison of progression-free survival of those patients on their last line of prior therapy (gold bars) to their progression-free survival on a treatment selected with the patented molecular system (blue bars).



23. The 2010 Pilot Study also concluded that "this MP approach resulted in a longer PFS for patients on an MP-suggested regimen than on the regimen the patients had just experienced progression on for 27% of the patients." In other words, the patented invention showed a five-fold improvement in patient response as compared to the expected patient response for conventional therapies, which at the time was approximately 5%. Thus, the patented system improves the treatment of cancer patients.

24. In the same issue, the Journal of Clinical Oncology also published an accompanying editorial to the 2010 Pilot Study by Dr. James Doroshow of the National Cancer

Institute. (Ex. 7, Doroshow Editorial on Pilot Study.) He explained that in the 2010 Pilot Study, "Von Hoff et al take the novel approach of developing individualized molecular tumor profiles to define therapy for every patient enrolled onto their prospective study – in essence, performing a series of gene expression-guided pilot studies, each with a sample size of one (so-called N=1 design)."

25. Dr. Doroshow also compared the patented molecular profiling technique to the conventional method of selecting treatment, noting that "[t]he hypothesis underlying the bold and potentially practice-changing effort undertaken by Von Hoff et al is that currently available molecular profiling technologies are sufficiently robust to allow selection of an additional treatment for this patient population in a fashion superior to that of an experienced clinician's best judgment."

26. Dr. Doroshow further praised the patented molecular profiling technique as innovative for "[e]stablishing a novel algorithm for the use of unique molecular profiles to determine an individual patient's treatment."

27. Building off the success of Dr. Von Hoff and Dr. Penny's invention, today molecular profiling is rapidly becoming accepted as part of the standard of care for the treatment of cancer patients.

THE ASSERTED PATENTS

The '350 Patent

28. On November 4, 2014, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '350 Patent titled "System and Method for Determining Individualized Medical Intervention for a Disease State," to Daniel Von Hoff and Robert Penny. A true and correct copy of the '350 Patent is attached hereto as Exhibit 1.

29. Caris MPI, Inc. is the assignee of the entire right, title, and interest in and to the ’350 Patent.

The ’193 Patent

30. On June 21, 2016, the USPTO duly and legally issued the ’193 Patent titled “System and Method for Determining Individualized Medical Intervention for a Disease State,” to Daniel Von Hoff and Robert Penny. A true and correct copy of the ’193 Patent is attached hereto as Exhibit 3.

31. Caris MPI, Inc. is the assignee of the entire right, title, and interest in and to the ’193 Patent.

The ’365 Patent

32. On July 5, 2016, the USPTO duly and legally issued the ’365 Patent titled “System and Method for Determining Individualized Medical Intervention for a Disease State,” to Daniel Von Hoff and Robert Penny. A true and correct copy of the ’365 Patent is attached hereto as Exhibit 4.

33. Caris MPI, Inc. is the assignee of the entire right, title and interest in and to the ’365 Patent.

The ’392 Patent

34. On July 28, 2015, the USPTO duly and legally issued the ’392 Patent titled “Molecular Profiling of Tumors,” to Daniel Von Hoff, David Loesch, Arlet Alarcon, Robert Penny, Alan Wright, Matthew McGinniss, Ryan Bender, and Traci Pawlowski. A true and correct copy of the ’392 Patent is attached hereto as Exhibit 2.

35. Caris MPI, Inc. is the assignee of the entire right, title, and interest in and to the ’392 Patent.

The '660 Patent

36. On March 22, 2016, the USPTO duly and legally issued the '660 Patent titled "Molecular Profiling of Tumors," to Daniel Von Hoff, David Loesch, Arlet Alarcon, Robert Penny, Alan Wright, Matthew McGinniss, Ryan Bender, and Traci Pawlowski. A true and correct copy of the '660 Patent is attached hereto as Exhibit 5.

37. Caris MPI, Inc. is the assignee of the entire right, title, and interest in and to the '660 Patent.

The Accused Products

38. On information and belief, Defendant was founded in 2010.

39. Defendant makes, uses, sells, offers for sale, and/or imports products under the Foundation brand that include molecular profiling technology. These products include, but are not limited to, the FoundationOne®, FoundationOne® Heme, and FoundationACT® products.

40. Defendant acknowledges in public statements that the "increasing availability and understanding of molecular information within the practice of oncology is driving a revolution in the treatment of cancer." (Ex. 8, FMI 2016 10-K, at 6.)

41. Defendant has described its infringing FoundationOne® product as "a validated comprehensive genetic profile (CGP) for solid tumors" that is "designed to provide physicians with clinically actionable information to guide treatment decisions for patients based on the genomic profile of their disease." (https://www.foundationmedicine.com/genomic-testing/foundation-one.) The FoundationOne® test results "provide information about clinically significant alterations, potential targeted therapies, available clinical trials, and quantitative markers of response for immunotherapy." (*Id.*) These results are summarized in the FoundationOne® test report, including genomic alterations, therapies associated with clinical

benefit, therapies associated with lack of response, and a list of potential clinical trials for which the patient may qualify. (Ex. 9, FoundationOne® Report, available at https://assets.contentful.com/vhribv12lmne/IGW77Eols2m8UeUCIocgW/5400d5a2c9a21fc616e54c93dd21f067/FoundationOne_Sample_Report.pdf)

FOUNDATIONONE

Patient Name | Report Date | Tumor Type: Lung adenocarcinoma

Date of Birth		Medical Facility			
Sex	Male	Ordering Physician		Specimen Received	
FMI Case #		Additional Recipient		Specimen Site	Lymph Node
Medical Record #		Medical Facility ID #		Date of Collection	
Specimen ID		Pathologist		Specimen Type	

ABOUT THE TEST:

FoundationOne™ is a next-generation sequencing (NGS) based assay that identifies genomic alterations within hundreds of cancer-related genes.

PATIENT RESULTS

- 11 genomic findings
- 10 therapies associated with potential clinical benefit
- 0 therapies associated with lack of response
- 19 clinical trials

TUMOR TYPE: LUNG ADENOCARCINOMA

Genomic Alterations Identified†

ERBB2 amplification – equivocal*
NF2 E427*
STK11 splice site 921-1G>C
CDKN1B E105fs*14
FOXP1 E490*
KDM5C W983*
LRP1B loss exons 6-14
SPTA1 Q1346fs*3, splice site 3570-2A>T
TP53 I255S

Additional Findings†

Tumor Mutation Burden TMB-High; 37.53 Muts/Mb

Additional Disease-relevant Genes with No Reportable Alterations Identified†

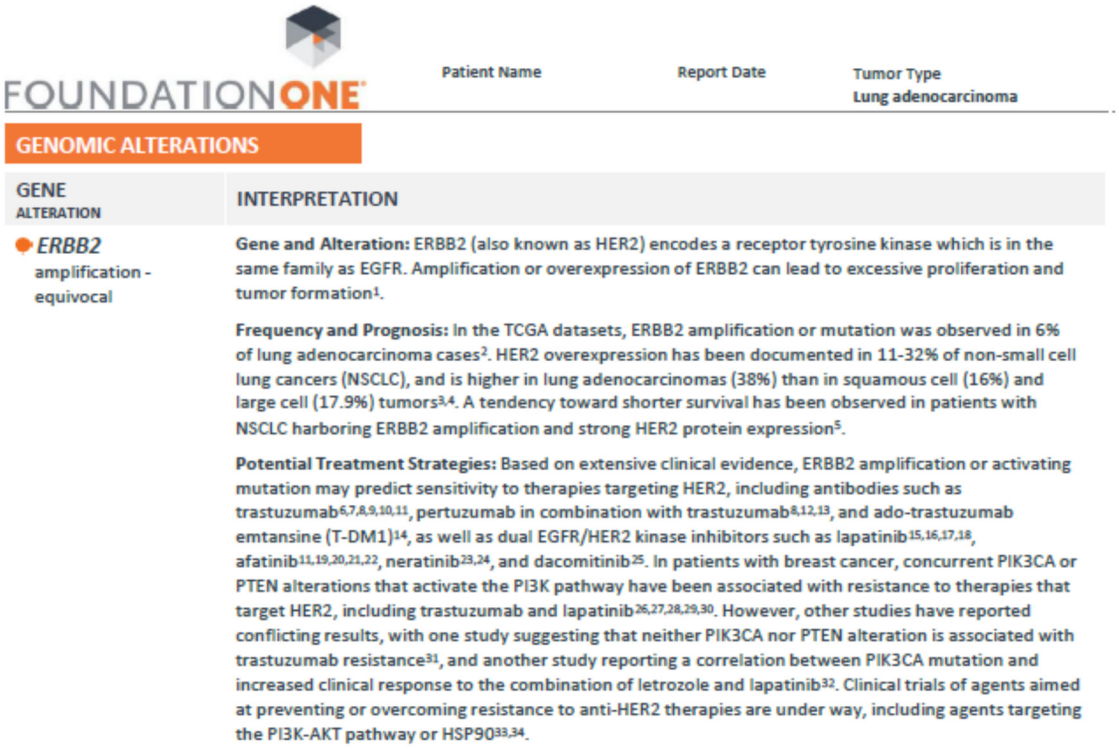
EGFR
KRAS
ALK
BRAF
MET
RET
ROS1

† For a complete list of the genes assayed and performance specifications, please refer to the Appendix
* See Appendix for details

THERAPEUTIC IMPLICATIONS

42. The results of the FoundationOne® test are presented in a report which lists the molecular targets and alterations detected, the frequency and prognosis, and potential treatment

strategies. The full list of molecular targets tested is included in an appendix at the end of the FoundationOne® report.



FOUNDATIONONE

Patient Name | Report Date | Tumor Type: Lung adenocarcinoma

GENOMIC ALTERATIONS

GENE ALTERATION	INTERPRETATION
ERBB2 amplification - equivocal	**Gene and Alteration:** ERBB2 (also known as HER2) encodes a receptor tyrosine kinase which is in the same family as EGFR. Amplification or overexpression of ERBB2 can lead to excessive proliferation and tumor formation[1]. **Frequency and Prognosis:** In the TCGA datasets, ERBB2 amplification or mutation was observed in 6% of lung adenocarcinoma cases[2]. HER2 overexpression has been documented in 11-32% of non-small cell lung cancers (NSCLC), and is higher in lung adenocarcinomas (38%) than in squamous cell (16%) and large cell (17.9%) tumors[3,4]. A tendency toward shorter survival has been observed in patients with NSCLC harboring ERBB2 amplification and strong HER2 protein expression[5]. **Potential Treatment Strategies:** Based on extensive clinical evidence, ERBB2 amplification or activating mutation may predict sensitivity to therapies targeting HER2, including antibodies such as trastuzumab[6,7,8,9,10,11], pertuzumab in combination with trastuzumab[8,12,13], and ado-trastuzumab emtansine (T-DM1)[14], as well as dual EGFR/HER2 kinase inhibitors such as lapatinib[15,16,17,18], afatinib[11,19,20,21,22], neratinib[23,24], and dacomitinib[25]. In patients with breast cancer, concurrent PIK3CA or PTEN alterations that activate the PI3K pathway have been associated with resistance to therapies that target HER2, including trastuzumab and lapatinib[26,27,28,29,30]. However, other studies have reported conflicting results, with one study suggesting that neither PIK3CA nor PTEN alteration is associated with trastuzumab resistance[31], and another study reporting a correlation between PIK3CA mutation and increased clinical response to the combination of letrozole and lapatinib[32]. Clinical trials of agents aimed at preventing or overcoming resistance to anti-HER2 therapies are under way, including agents targeting the PI3K-AKT pathway or HSP90[33,34].

43. Based on those test results, the FoundationOne® report provides a list of therapies with potential benefit as well as a list of therapies associated with lack of response.

FOUNDATIONONE

Patient Name | Report Date | Tumor Type: Lung adenocarcinoma

THERAPIES

FDA-APPROVED THERAPIES IN PATIENT TUMOR TYPE

THERAPY	SUMMARY OF DATA IN PATIENT TUMOR TYPE
Afatinib	**Approved Indications:** Afatinib is an irreversible kinase inhibitor that targets the kinase domains of EGFR, ERBB2/HER2, and ERBB4. It is FDA approved for the treatment of metastatic non-small cell lung cancer (NSCLC) in patients with EGFR exon 19 deletions or exon 21 (L858R) missense mutations. **Gene Association:** ERBB2 amplification or activating mutations may indicate sensitivity to afatinib on the basis of clinical evidence in various solid tumors[11,19,193]. **Supporting Data:** Phase 3 clinical trials have demonstrated that treatment with afatinib, compared to chemotherapy, leads to significantly increased progression-free survival for patients with EGFR-mutant NSCLC[194,195], and increased overall survival (OS) for patients with EGFR exon 19 alterations specifically[196]. A Phase 3 trial comparing afatinib with erlotinib as second-line therapies for advanced lung squamous cell carcinoma reported significantly higher OS (7.9 months vs. 6.8 months) and disease control rate (DCR) (51% vs. 40%) for patients treated with afatinib[197]. Phase 2/3 studies of afatinib treatment for patients with erlotinib- or gefitinib-resistant NSCLC have generally reported partial responses (PRs) of only 7-9%[22,198,199,200,201,202], and DCRs of more than 50%[22]; in particular, disease control was achieved for 2/2 patients with EGFR-amplified NSCLC[22] and 9/14 patients with T790M-positive NSCLC[202]. The T790M mutation has been implicated in reduced response to afatinib[201,203,204], with a secondary T790M mutation reported in 48% (20/42) of patients with afatinib-resistant lung adenocarcinoma[203]. The combination of afatinib with cetuximab resulted in a higher response rate (29%) for patients with erlotinib- or gefitinib-resistant disease[205], including T790M-positive cases[205,206], although adverse reactions may be a concern with this combination[207]. Upon progression on afatinib, further benefit has been reported from combination treatment with afatinib and paclitaxel[208].

44. Finally, the FoundationOne® report provides a list of clinical trials for which the patient may qualify based on the patient's molecular profiling results. This list includes the title, the specific molecular targets identified, and the location of the clinical trial.

FOUNDATIONONE

Patient Name | Report Date | Tumor Type: Lung adenocarcinoma

CLINICAL TRIALS TO CONSIDER

IMPORTANT: While every effort is made to ensure the accuracy of the information contained below, the information available in the public domain is continually updated and should be investigated by the physician or research staff. This is not meant to be a complete list of available trials. In order to conduct a more thorough search, please go to www.clinicaltrials.gov and use the search terms provided below. For more information about a specific clinical trial, type the NCT ID of the trial indicated below into the search bar.

GENE	RATIONALE FOR POTENTIAL CLINICAL TRIALS
ERBB2 amplification - equivocal	ERBB2 amplification or activating mutations may confer sensitivity to HER2-targeted and dual EGFR/HER2-directed therapies, and may enhance efficacy of chemotherapy or other targeted therapies, such as HSP90 inhibitors. Examples of clinical trials that may be appropriate for this patient are listed below. These trials were identified through a search of the trial website clinicaltrials.gov using keyword terms such as "ERBB2", "HER2", "trastuzumab", "lapatinib", "pertuzumab", "ado-trastuzumab emtansine", "afatinib", "HSP90", "NSCLC", "lung", "solid tumor", and/or "advanced cancer".

TITLE	PHASE	TARGETS	LOCATIONS	NCT ID
Phase I Active Immunotherapy Trial With a Combination of Two Chimeric (Trastuzumab-like and Pertuzumab-like)Human Epidermal Growth Factor Receptor 2 (HER-2) B Cell Peptide Vaccine Emulsified in ISA 720 and Nor-MDP Adjuvant in Patients With Advanced Solid Tumors	Phase 1	ERBB2	Ohio	NCT01376505
An Open-label, Multicenter, Multinational, Phase 2 Study Exploring the Efficacy and Safety of Neratinib Therapy in Patients With Solid Tumors With Activating HER2, HER3 or EGFR Mutations or With EGFR Gene Amplification.	Phase 2	EGFR, ERBB2, ERBB4	California, Florida, Massachusetts, Missouri, New Jersey, New York, Tennessee, Texas, Barcelona (Spain), Cremona (Italy), Helsinki (Finland), London (United Kingdom), Madrid (Spain), Petch Tiqwa (Israel), Rehovot (Israel), Seoul (Korea, Republic of), Torino (Italy), Valencia (Spain), Victoria (Australia)	NCT01953926

45. On information and belief, FMI commercially launched its FoundationOne® product in the United States at least as early as May 30, 2012.

46. Defendant describes its infringing FoundationOne® Heme product as "a comprehensive genomic profiling assay for hematologic malignancies and sarcomas" that is "designed to provide physicians with clinically actionable information to help with diagnostic subclassification, prognosis assessment, and targeted therapeutic selection." (https://www.foundationmedicine.com/genomic-testing/foundation-one-heme.) The FoundationOne® Heme test results "provide information about clinically significant alterations, potential targeted therapies, available clinical trials, and quantitative markers that may support immunotherapy clinical trial enrollment." (*Id.*) On information and belief, these results are

summarized in the FoundationOne® Heme test report, including genomic alterations, therapies associated with clinical benefit, therapies associated with lack of response, and a list of potential clinical trials for which the patient may qualify.

47. On information and belief, FMI commercially launched its FoundationOne® Heme product in the United States at least as early as December 7, 2013.

48. Defendant describes its infringing FoundationACT® product as "a blood-based circulating tumor DNA (ctDNA) assay for solid tumors that identifies clinically relevant genomic alterations driving the growth of a patient's cancer." (https://www.foundationmedicine.com/genomic-testing/foundation-act.) "This liquid biopsy can help physicians identify treatment options by providing clinically actionable information relevant to diagnosis, risk-stratification, and prognosis." (*Id.*) The FoundationACT® test results "provide information about potential targeted therapies and/or available clinical trials to better inform treatment decisions." (*Id.*) These results are summarized in the FoundationACT™ test report, including genomic alterations, therapies associated with clinical benefit, therapies associated with lack of response, and a list of potential clinical trials for which the patient may qualify. (Ex. 10, FoundationACT® Sample Report, available at https://cdn2.hubspot.net/hubfs/174278/Corporate%20Landing%20Pages/031917%20-%20FACT%20Momentum%20Campaign%20Landing%20Page/Documents/FACT%20Sample%20Report_EGFR_T790mF_052516%5B1%5D.pdf?t=1493919601061.)

49. On information and belief, FMI commercially launched its FoundationACT® product in the United States at least as early as May 3, 2016.

50. The Accused FoundationOne®, FoundationOne® Heme, and FoundationACT® Products infringe the Asserted Patents. As a result of Defendant's infringement and the threat of its continued infringement, Caris faces a substantial risk of irreparable harm.

Count I: Infringement of the '350 Patent

51. Caris realleges Paragraphs 1-50 herein as if repeated verbatim in this Paragraph.

52. Claim 1 of the '350 Patent states as follows:

1. A system for generating a report identifying at least one therapeutic agent for an individual with a cancer comprising:
    a. at least one device configured to assay a plurality of molecular targets in a biological sample to determine individualized molecular profile test values for the plurality of molecular targets, wherein the molecular targets comprise EGFR, KIT, TOP1, MLH1, PTEN, PDGFRA and ESR1; and
    b. at least one computer database comprising:
        i. a reference value for the plurality of molecular targets; and
        ii. a listing of available therapeutic agents for said plurality of molecular targets;
    c. a computer-readable program code comprising instructions to input the individualized molecular profile test values and to compare said test values with a corresponding reference value in (b)(i);
    d. a computer-readable program code comprising instructions to access the at least one computer database and to identify at least one therapeutic agent from the listing of available therapeutic agents for the plurality of molecular targets wherein said comparison to said reference in (c) indicates a likely benefit of the at least one therapeutic agent; and
    e. a computer-readable program code comprising instructions to generate a report that comprises a listing of the molecular targets wherein said comparison to said reference indicated a likely benefit of the at least one therapeutic agent in (d) along with the at least one therapeutic agent identified in (d).

53. Defendant directly infringes at least claims 1 and 5 of the '350 Patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents, by making, using, selling, offering to sell, and/or importing the Accused FoundationOne® and FoundationOne® Heme Products. Attached hereto as Exhibit 11 is a non-limiting example demonstrating how the

Accused FoundationOne® and FoundationOne® Heme Products meet each and every limitation of at least claims 1 and 5 of the ’350 Patent.

54. As a result of Defendant’s direct infringement of the ’350 Patent, Caris has suffered monetary damages and is entitled to recovery of such damages.

55. Defendant’s infringement of the ’350 Patent has caused and will continue to cause irreparable harm to Caris.

56. Defendant identifies Caris as one of its competitors in its public statements. (Ex. 8, FMI 2016 10-K, at 44.) Defendant also acknowledges that its competitors “may also use their patent portfolios, developed in connection with developing their tests, to allege that [Defendant’s] products infringe their patents, and [Defendant] could face litigation with respect to such allegations and the validity of such patents.” (*Id.* at 45.) On information and belief, Defendant monitors the patents of its competitors and has known about the ’350 Patent at least since it issued on November 4, 2014, and knew or was willfully blind to the fact that its actions constituted infringement of at least claims 1 and 5 of the ’350 Patent. Defendant continues to infringe the ’350 Patent despite such knowledge and its knowledge as of the filing and/or service of this complaint.

57. Despite Defendant’s knowledge of and notice of the ’350 patent and its ongoing infringement, Defendant continues to manufacture, use, sell, offer for sale, and/or import the Accused FoundationOne® and FoundationOne® Heme Products in a manner that infringes the ’350 Patent. Defendant lacks a justifiable belief that it does not infringe the ’350 patent, or that the ’350 patent is invalid, and has acted recklessly in its infringing activity, justifying an increase in the damages to be awarded Caris up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

58. At least Defendant's willful infringement of the '350 patent renders this case an exceptional case, justifying an award to Caris of its reasonable attorneys' fees, in accordance with 35 U.S.C. § 285.

Count II: Infringement of the '193 Patent

59. Caris realleges Paragraphs 1-58 herein as if repeated verbatim in this Paragraph.

60. Claim 1 of the '193 Patent states as follows:

1. A system for generating a report identifying at least one therapeutic agent for an individual with a cancer comprising:
    a. at least one device configured to assay a plurality of molecular targets in a biological sample to determine molecular profile test values for the plurality of molecular targets, wherein the plurality of molecular targets comprises AR, EGFR, HER2, KIT, MLH1, PTEN, and PDGFRA; and
    b. at least one computer database comprising:
        i. a reference value for each of the plurality of molecular targets; and
        ii. a listing of available therapeutic agents for each of the plurality of molecular targets;
    c. a computer-readable program code comprising instructions to input the molecular profile test values and to compare each of the molecular profile test values with a corresponding reference value from the at least one computer database in (b)(i);
    d. a computer-readable program code comprising instructions to access the at least one computer database and to identify at least one therapeutic agent from the listing of available therapeutic agents for the plurality of molecular targets wherein the comparison to the reference values in (c) indicates a likely benefit of the at least one therapeutic agent; and
    e. a computer-readable program code comprising instructions to generate a report that comprises a listing of the molecular targets for which the comparison to the reference value indicated a likely benefit of the at least one therapeutic agent in (d) and the at least one therapeutic agent identified in (d).

61. Defendant directly infringes at least claims 1 and 5 of the '193 Patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents, by making, using, selling, offering to sell, and/or importing the Accused FoundationOne® and FoundationOne® Heme Products. Attached hereto as Exhibit 12 is a non-limiting example demonstrating how the

Accused FoundationOne® and FoundationOne® Heme Products meet each and every limitation of at least claims 1 and 5 of the ’193 Patent.

62. As a result of Defendant’s direct infringement of the ’193 Patent, Caris has suffered monetary damages and is entitled to recovery of such damages.

63. Defendant’s infringement of the ’193 Patent has caused and will continue to cause irreparable harm to Caris.

64. Defendant identifies Caris as one of its competitors in its public statements. (Ex. 8, FMI 2016 10-K, at 44.) Defendant also acknowledges that its competitors “may also use their patent portfolios, developed in connection with developing their tests, to allege that [Defendant’s] products infringe their patents, and [Defendant] could face litigation with respect to such allegations and the validity of such patents.” (*Id.* at 45.) On information and belief, Defendant monitors the patents of its competitors and has known about the ’193 Patent at least since it issued on June 21, 2016, and knew or was willfully blind to the fact that its actions constituted infringement of at least claims 1 and 5 of the ’193 Patent. Defendant continues to infringe the ’193 Patent despite such knowledge and its knowledge as of the filing and/or service of this complaint.

65. Despite Defendant’s knowledge of and notice of the ’193 patent and its ongoing infringement, Defendant continues to manufacture, use, sell, offer for sale, and/or import the Accused FoundationOne® and FoundationOne® Heme Products in a manner that infringes the ’193 Patent. Defendant lacks a justifiable belief that it does not infringe the ’193 patent, or that the ’193 patent is invalid, and has acted recklessly in its infringing activity, justifying an increase in the damages to be awarded Caris up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

66. At least Defendant's willful infringement of the '193 patent renders this case an exceptional case, justifying an award to Caris of its reasonable attorneys' fees, in accordance with 35 U.S.C. § 285.

Count III: Infringement of the '365 Patent

67. Caris realleges Paragraphs 1-66 herein as if repeated verbatim in this Paragraph.

68. Claim 1 of the '365 Patent states as follows:

1. A system for generating a report identifying at least one therapeutic agent for an individual with a cancer comprising:
    a. at least one device configured to assay a plurality of molecular targets in a biological sample to determine molecular profile test values for the plurality of molecular targets, wherein the plurality of molecular targets comprises EGFR, KIT, TOP1, MLH1, PTEN, PDGFRA and ERBB2[1]; and
    b. at least one computer database comprising:
        i. a reference value for each of the plurality of molecular targets; and
        ii. a listing of available therapeutic agents for each of the plurality of molecular targets;
    c. a computer-readable program code comprising instructions to input the molecular profile test values and to compare each of the molecular profile test values with a corresponding reference value from the at least one computer database in (b)(i);
    d. a computer-readable program code comprising instructions to access the at least one computer database and to identify at least one therapeutic agent from the listing of available therapeutic agents for the plurality of molecular targets wherein the comparison to the reference values in (c) indicates a likely benefit of the at least one therapeutic agent; and
    e. a computer-readable program code comprising instructions to generate a report that comprises a listing of the molecular targets for which the comparison to the reference value indicated a likely benefit of the at least one therapeutic agent in (d) and the at least one therapeutic agent identified in (d).

[1] Claim 1 of the '365 Patent contains an obvious typographical error that inadvertently identifies ERBB2 as "ERRB2." The only reasonable interpretation of the claim, based on consideration of the claim language and the '365 Patent specification, is that it should read "ERBB2." For example, the '365 Patent specification identifies "ERBB2," the specification does not identify "ERRB2," and ERRB2 was not and is not a recognized molecular target. The prosecution history does not suggest a different interpretation of the claim.

69. Defendant directly infringes at least claims 1 and 5 of the ’365 Patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents, by making, using, selling, offering to sell, and/or importing the Accused FoundationOne® and FoundationOne® Heme Products. Attached hereto as Exhibit 13 is a non-limiting example demonstrating how the Accused FoundationOne® and FoundationOne® Heme Products meet each and every limitation of at least claims 1 and 5 of the ’365 Patent.

70. As a result of Defendant’s direct infringement of the ’365 Patent, Caris has suffered monetary damages and is entitled to recovery of such damages.

71. Defendant’s infringement of the ’365 Patent has caused and will continue to cause irreparable harm to Caris.

72. Defendant identifies Caris as one of its competitors in its public statements. (Ex. 8, FMI 2016 10-K, at 44.) Defendant also acknowledges that its competitors “may also use their patent portfolios, developed in connection with developing their tests, to allege that [Defendant’s] products infringe their patents, and [Defendant] could face litigation with respect to such allegations and the validity of such patents.” (*Id.* at 45.) On information and belief, Defendant monitors the patents of its competitors and has known about the ’365 Patent at least since it issued on July 5, 2016, and knew or was willfully blind to the fact that its actions constituted infringement of at least claims 1 and 5 of the ’365 Patent. Defendant continues to infringe the ’350 Patent despite such knowledge and its knowledge as of the filing and/or service of this complaint.

73. Despite Defendant’s knowledge of and notice of the ’365 patent and its ongoing infringement, Defendant continues to manufacture, use, sell, offer for sale, and/or import the

Accused FoundationOne® and FoundationOne® Heme Products in a manner that infringes the '365 Patent. Defendant lacks a justifiable belief that it does not infringe the '365 patent, or that the '365 patent is invalid, and has acted recklessly in its infringing activity, justifying an increase in the damages to be awarded Caris up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

74. At least Defendant's willful infringement of the '365 patent renders this case an exceptional case, justifying an award to Caris of its reasonable attorneys' fees, in accordance with 35 U.S.C. § 285.

Count IV: Infringement of the '392 Patent

75. Caris realleges Paragraphs 1-74 herein as if repeated verbatim in this Paragraph.

76. Claim 1 of the '392 Patent states as follows:

1. A system for generating a report identifying a therapeutic agent for an individual with colorectal cancer comprising:
    a. at least one nucleic acid sequencing device configured to assay a plurality of molecular targets in a biological sample from the individual with colorectal cancer to determine molecular profile test values for the plurality of molecular targets, wherein the plurality of molecular targets comprises BRAF, PIK3CA, EGFR and PTEN; and
    b. at least one computer database comprising:
        i. a reference value for each of the plurality of molecular targets; and
        ii. a listing of available therapeutic agents for each of the plurality of molecular targets;
    c. a computer-readable program code comprising instructions to input the molecular profile test values to compare each of the molecular profile test values with a corresponding reference value from the at least one computer database in (b)(i);
    d. a computer-readable program code comprising instructions to access the at least one computer database to identify at least one therapeutic agent from the listing of available therapeutic agents for the plurality of molecular targets wherein the comparison to the reference values in (c) indicates a likely benefit of the at least one therapeutic agent; and
    e. a computer-readable program code comprising instructions to generate a report that comprises a listing of the molecular targets for which the

comparison to the reference value indicated a likely benefit of the at least one therapeutic agent in (d) and the at least one therapeutic agent identified in (d).

77. Defendant directly infringes at least claims 1 and 5 of the ’392 Patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents, by making, using, selling, offering to sell, and/or importing the Accused FoundationOne® and FoundationACT® Products. Attached hereto as Exhibit 14 is a non-limiting example demonstrating how the Accused FoundationOne® and FoundationACT® Products meet each and every limitation of at least claims 1 and 5 of the ’392 Patent.

78. As a result of Defendant’s direct infringement of the ’392 Patent, Caris has suffered monetary damages and is entitled to recovery of such damages.

79. Defendant’s infringement of the ’392 Patent has caused and will continue to cause irreparable harm to Caris.

80. Defendant identifies Caris as one of its competitors in its public statements. (Ex. 8, FMI 2016 10-K, at 44.) Defendant also acknowledges that its competitors “may also use their patent portfolios, developed in connection with developing their tests, to allege that [Defendant’s] products infringe their patents, and [Defendant] could face litigation with respect to such allegations and the validity of such patents.” (*Id.* at 45.) On information and belief, Defendant monitors the patents of its competitors and has known about the ’392 Patent at least since it issued on July 28, 2015, and knew or was willfully blind to the fact that its actions constituted infringement of at least claims 1 and 5 of the ’392 Patent. Defendant continues to infringe the ’392 Patent despite such knowledge and its knowledge as of the filing and/or service of this complaint.

81. Despite Defendant’s knowledge of and notice of the ’392 patent and its ongoing infringement, Defendant continues to manufacture, use, sell, offer for sale, and/or import the

Accused FoundationOne® and FoundationACT® Products in a manner that infringes the '392 Patent. Defendant lacks a justifiable belief that it does not infringe the '392 patent, or that the '392 patent is invalid, and has acted recklessly in its infringing activity, justifying an increase in the damages to be awarded Caris up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

82. At least Defendant's willful infringement of the '392 patent renders this case an exceptional case, justifying an award to Caris of its reasonable attorneys' fees, in accordance with 35 U.S.C. § 285.

Count V: Infringement of the '660 Patent

83. Caris realleges Paragraphs 1-82 herein as if repeated verbatim in this Paragraph.

84. Claim 1 of the '660 Patent states as follows:

1. A system for generating a report identifying a therapeutic agent for an individual with lung cancer comprising:
    a. at least one device configured to assay a plurality of molecular targets in a biological sample from the individual with lung cancer to determine molecular profile test values for the plurality of molecular targets, wherein the plurality of molecular targets comprises PTEN, CTNNB1, cKIT, BRAF and PIK3CA; and
    b. at least one computer database comprising:
        i. a reference value for each of the plurality of molecular targets; and
        ii. a listing of available therapeutic agents for the plurality of molecular targets;
    c. a computer-readable program code comprising instructions to input the molecular profile test values and to compare each of the molecular profile test values with a corresponding reference value from the at least one computer database in (b)(i);
    d. a computer-readable program code comprising instructions to access the at least one computer database in (b)(ii) and to identify at least one therapeutic agent if present in the at least one computer database for each of the plurality of molecular targets wherein said comparison to the reference values in (c) indicates a likely benefit of the at least one therapeutic agent; and
    e. a computer-readable program code comprising instructions to generate a report that comprises a listing of the members of the plurality of molecular

> targets for which the comparison to the reference value indicated a likely benefit of the at least one therapeutic agent in (d) and the at least one therapeutic agent identified in (d).

85. Defendant directly infringes at least claims 1 and 5 of the ’660 Patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents, by making, using, selling, offering to sell, and/or importing the Accused FoundationOne® and FoundationACT® Products. Attached hereto as Exhibit 15 is a non-limiting example demonstrating how the Accused FoundationOne® and FoundationACT® Products meet each and every limitation of at least claims 1 and 5 of the ’660 Patent.

86. As a result of Defendant’s direct infringement of the ’660 Patent, Caris has suffered monetary damages and is entitled to recovery of such damages.

87. Defendant’s infringement of the ’660 Patent has caused and will continue to cause irreparable harm to Caris.

88. Defendant identifies Caris as one of its competitors in its public statements. (Ex. 8, FMI 2016 10-K, at 44.) Defendant also acknowledges that its competitors “may also use their patent portfolios, developed in connection with developing their tests, to allege that [Defendant’s] products infringe their patents, and [Defendant] could face litigation with respect to such allegations and the validity of such patents.” (*Id.* at 45.) On information and belief, Defendant monitors the patents of its competitors and has known about the ’660 Patent at least since it issued on March 22, 2016, and knew or was willfully blind to the fact that its actions constituted infringement of at least claims 1 and 5 of the ’660 Patent. Defendant continues to infringe the ’392 Patent despite such knowledge and its knowledge as of the filing and/or service of this complaint.

89. Despite Defendant's knowledge of and notice of the '660 patent and its ongoing infringement, Defendant continues to manufacture, use, sell, offer for sale, and/or import the Accused FoundationOne® and FoundationACT® Products in a manner that infringes the '660 Patent. Defendant lacks a justifiable belief that it does not infringe the '660 patent, or that the '660 patent is invalid, and has acted recklessly in its infringing activity, justifying an increase in the damages to be awarded Caris up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

90. At least Defendant's willful infringement of the '660 patent renders this case an exceptional case, justifying an award to Caris of its reasonable attorneys' fees, in accordance with 35 U.S.C. § 285.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Caris hereby demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Caris respectfully requests that the Court enter judgment in Caris' favor and against FMI, and provide Caris the following relief:

(1) A finding that Defendant has infringed one or more claims of the '350 Patent;

(2) A finding that Defendant has infringed one or more claims of the '193 Patent;

(3) A finding that Defendant has infringed one or more claims of the '365 Patent;

(4) A finding that Defendant has infringed one or more claims of the '392 Patent;

(5) A finding that Defendant has infringed one or more claims of the '660 Patent;

(6) A finding that Defendant's infringement of the '350, '193, '365, '392, and '660 Patents has been and is willful;

(7) Ongoing injunctive relief against Defendant as appropriate for its infringement;

(8) An award to Plaintiff of damages adequate to compensate Plaintiff for all infringement occurring through the date of judgment, including Caris' lost profits, with prejudgment interest, and for any supplemental damages as appropriate and post-judgment interest after that date;

(9) An award of enhanced damages under 35 U.S.C. § 284;

(10) A finding that this action for infringement is an exceptional case under 35 U.S.C. § 285 and an award to Plaintiff of its reasonable attorneys' fees and costs;

(11) An accounting of Defendant's infringing activities through trial and judgment; and

(12) An award of any further relief that the Court deems just and proper.

Dated: November 7, 2017

By: */s/ Adam J. Kessel*

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